Foundations of Pharmaceutical cGMP Practice Questions

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Disclaimer

The purpose of this question bank is to provide readers with a comprehensive resource for professional development. This compilation of questions is designed to facilitate deeper understanding and effective preparation for various assessments and applications. The content spans a wide range of topics, meticulously curated to support diverse learning objectives and needs.

Recognizing the ever-evolving nature of knowledge and practice in the pharmaceutical fields, it has been endeavored to include current and relevant information from text books, regional and international guidelines, open-source websites, and pre and post webinar's training questions. However, it should be acknowledged that the dynamic landscape of these domains may lead to new developments and perspectives that are not captured within this resource. Therefore, readers are recommended to approach this question bank as a supplementary tool rather than a definitive source.

In this regard, it is essential for users to verify the information and concepts presented herein against additional references. Besides, engaging with multiple sources will not only reinforce the accuracy of the material but also enrich the reader's comprehension and application of the subject matter. It has been strived to present the questions in a clear and accessible manner, aiming to stimulate intellectual curiosity and foster a rigorous approach to learning. Nevertheless, the responsibility rests on the reader's due diligence in interpreting and utilizing the content. This will help mitigate any potential misinterpretations or inaccuracies that may arise.

Ultimately, the effectiveness of this question bank is contingent upon the reader's proactive engagement and verification of the material. This resource will serve as a valuable aid in the professional journey, providing a robust foundation for further exploration and mastery.

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Instruction: There is only one correct answer for all questions.

1. Which one is common requirement for both RABS, open and close isolators in sterile product manufacturing?
   A. Grade A + First Air + UDAF C. Background minimum grade B
   B. Background minimum grade C D. Background minimum grade D
2. One of the organisms given below is used as BIs in ethylene oxide sterilization.
   A. Bacillus stearothermophilus C. Bacillus atrophaeus
   B. Bacillus cereus D. Bacillus stearothermophilus
3. Which of the following is preventive action?
   A. Replacing the label on a device that had the wrong label applied
   B. Revising process parameters in response to complaints
   C. Auditing all vendors of a key component after quality issues with only one vendor are identified
   D. Revising equipment maintenance procedures to reduce drift in process specifications
4. D-value is **NOT** used for which types of sterilization validation?
   A. Heat B. Gas C. Radiation D. Filter
5. The concentration of residual solvents can be determined by
   A. Computing the contribution from each component of the product and summing these results
   B. Experimentally testing the final product
   C. Computing the contribution from each component of the product and summing these results
   D. Either using method B or C
6. Which microorganisms is used to biologically monitor the dry heat sterilizer?
   A. B. atropheus B. G. atropheus C. B. subtills D. B. pumilus
7. Prospective validation is carried out during
   A. During development stage of pharmaceutical product
   B. After launch of pharmaceutical product
   C. During development and after launch of pharmaceutical product
   D. During routine production batches
   E. A and C

8. Which of the following is **TRUE** about pharmaceutical development ICH Q8?
    - A. The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product
    - B. Information from pharmaceutical development studies can be a basis for quality risk management
    - C. Movement out of the design space is considered to be a change and would normally initiate a regulatory post approval change process.
    - D. All are true
9. During which stage of the process validation; review of deviations, investigation results, product failures, complaints, and other product performance and quality indicators should be included in.
    - A. Continued process verification program. C. Pilot-scale programme
    - B. Process validation scheme D. A and B
10. The exposure time for spores and vegetative forms of microorganisms at 170°C is?
    - A. ½ Hr. B. 1 ½ Hrs. C. 2.0 Hrs. D. 3.0 Hrs.
11. Which one of the following is **FALSE** about both qualification and validation?
    - A. Qualification of rooms or areas should be succeeding the qualification of utilities.
    - B. Utilities should be qualified prior to the qualification of equipment.
    - C. Equipment, should be qualified preceding to the qualification of procedures and processes.
    - D. For surfaces not in contact with the product, such as cooling tower, commissioning may be the only qualification required.
    - E. Contact of the product with the surface of the equipment is certainly a major criterion in determining the extent of the qualification process.
12. Bacterial endotoxin test is used to determine
    - A. The amount of pyrogens
    - B. The level of pyrogens from Gram negative bacteria
    - C. The level of bacterial endotoxin from Gram negative bacteria
    - D. The level of bacterial endotoxin from Gram positive bacteria
    - E. C and D
13. For the sterilization of powders, which methods of sterilization is used?
    - A. Dry Heat B. Moist Heat C. Filtration D. Gas

14. For an aseptically processed sterile product, the holding of the filtered product and sterilized component prior to filling should be under UDLAF system and filling can be done within 24 hours

    A. True B. False

15. Properties of component of drug product that should be considered during pharmaceutical development include
    - A. The physicochemical and biological properties of the drug substance that can influence the performance of the drug product and its manufacturability
    - B. The compatibility of the drug substance with excipients
    - C. The excipients chosen, their concentration, and the characteristics that can influence the drug product performance or manufacturability
    - D. All
16. Disqualification of personnel from ascetic working area could result based on
    - A. Ongoing assessment of the personnel working aseptic manufacturing
    - B. Identification of an adverse trend from the personnel monitoring the programme
    - C. After being implicated the personnel failed APS qualification programme.
    - D. All could result in disqualification of personnel working aseptic manufacturing
    - E. Only C could result to disqualification from working in aseptic manufacturing
17. Which one of the following is **TRUE** about process validation?
    - A. It involves extensive frequent sampling and analysis beyond that required during normal routine monitoring
    - B. Re-validation is required when there is variation in any of the critical process, equipment, formulation, premises
    - C. End product testing reveals all variations that may occur in the product that may impact on safety and effectiveness.
    - D. Data generated through process validation can be used to justify why a specific test need not be routinely controlled in the specification of FPP or in-process specs
    - E. All are true
18. The document entry in batch manufacturing record is done by

    A. Quality control department C. Quality assurance department

    B. Warehouse department D. Production department

19. Impurity for which a structural characterization has **NOT** been achieved and that is solely defined by qualitative analytical properties is known as

    A. Specified impurity
    C. Unidentified impurity
    B. Unspecified impurity
    D. Identified impurity

20. PQR approaches call for which one of the following procedures to be developed and documented

    A. To ensure that the need for action is evaluated relevant to the possible consequences,
    B. To ensure the root cause of the problem is investigated, possible actions are determined,
    C. To ensure a selected action is taken within a defined timeframe
    D. To ensure the effectiveness of the action taken is evaluated.
    E. All

21. GMP applies to the lifecycle stages from the product development, technology transfer, commercial manufacturing through to product discontinuation.

    A. True
    B. False

22. PQR report by exception may be generated to cover:

    A. All products
    C. A group of products
    B. A client's products
    D. Each specific product
    E. All

23. All are organizational measure approach of prevention contamination in production area. **EXCEPT**

    A. Minimising the risk of contamination caused by recirculation or re-entry of untreated air
    B. Cleaning verification after each product campaign
    C. Keeping specific protective clothing inside areas where products with high risk of cross-contamination are processed
    D. Design of detailed records for cleaning processes to assure completion of cleaning in accordance with approved procedures
    E. Design of detailed records for cleaning labels on equipment and manufacturing areas
    F. Supervision of working behavior to ensure training effectiveness and compliance with the relevant procedural controls.

24. By which mechanism does dry heat sterilization works?

    A. Oxidizing proteins
    C. Oxidizing DNA
    B. Reduction of lipids
    D. All of the Above

25. Which one of the following are/is **FALSE** about both qualification and validation?
    - A. Data supporting qualification and/or validation studies obtained from sources outside of the manufacturers own programmes can also be used if justified.
    - B. Validation offers assurance that a process is reasonably protected against sources of variability that could affect production output, and supply problems,
    - C. Qualification is actually part of validation but not vice versa.
    - D. Qualification should be preceded by process validation
    - E. Process performance qualification should be succeeded by process validation
26. All of the following are **CORRECT** about URS. **EXCEPT**
    - A. The material of construction like 304L is outlined at the URS qualification stage
    - B. The URS should be used to verify suitability throughout the subsequent stages of qualification.
    - C. The essential elements of quality need to be built in at this stage and any GMP risks mitigated to an acceptable level.
    - D. Calibration of the equipment is verified at this stage of the qualification.
    - E. The requirements of the URS should be verified during the design qualification
27. Moist heat sterilization works on the principle of?
    - A. Oxidizing proteins
    - B. Reduction of proteins
    - C. Coagulation of proteins
    - D. All of the Above
28. What is the need for a pest control program in manufacturing premises?
    - A. To eliminate all pests from the premises
    - B. To prevent pests from entering the premises
    - C. To reduce the number of pests on the premises to an acceptable level
    - D. To use pesticides as often as possible to ensure no pests are present
29. Usually, autoclave works on which parameters?
    - A. 20 Min 15 psi & 121°C
    - B. 30 Min 15 psi & 121°C
    - C. 15 Min 20 psi & 121°C
    - D. 20 Min 15 psi & 131°C
30. A periodic verification/reconciliation must be carried out to ensure the current status of all ____.
    - A. Specifications
    - B. Standard operating procedures
    - C. Quality standards manuals
    - D. A and C

31. Which one is a GMP requirement for storage areas?
    A. All materials must be stored in their original packaging
    B. Storage areas must be located near employee break rooms
    C. Only one employee is allowed in the storage area at a time
    D. Storage areas do not need to be temperature controlled
32. Which of the following is **TRUE** about the different types of process validation?
    A. Prospective validation is carried out during development stage by means of risk analysis of the production process, which is break down in to individual steps; these are then evaluated on the base of past experience to determine whether they might lead to the critical situation
    B. Prospective validation is essential in order to limit the risk of error occurring on the production scale such as the preparation of injectable products
    C. Retrospective validation involves the examination of past experience of production on the assumption that the composition, procedure and the equipment remain unchanged and may be applied for manufacture of sterile product
    D. Revalidation is needed to ensure that the changes in the process and/or process environment, whether intentional or unintentional, do not adversely affect the process characteristics and product quality
    E. All are true Except C
33. The goal of technology transfer during product lifecycle stages of PQS is
    A. To achieve product realization, maintaining a state of control, and facilitating continual improvement.
    B. To handover product and process knowledge between development and manufacturing and within or between manufacturing sites to achieve product realization.
    C. To design a product and its manufacturing process to consistently deliver intended performance and meet the needs of patients, healthcare professionals, and NRA, and internal customers' requirements.
    D. To establish a commercial manufacturing process capable of consistently producing a product with its intended quality.
34. Linearity determination is required for which one of the analytical method/s validations?
    A. Limit test B. Identification test C. Potency D. All

35. For ISO Level 3 protection, which filter grades are recommended for protected area operating under fresh air 100%,
    A. EN 799 G-4 plus F-8 or F9 and EN 1822-H13
    B. EN 799 G-5 plus F-6 or F7 and EN 1822-H14
    C. EN 799 G-4 plus EN 1822 F8 or F9
    D. EN 799 G-4 plus EN 1822 F6 or F7
36. The products quality is very much based on the _______, change control, validation and training of the analytical testing methods.
    A. Documentation
    B. Development
    C. Specifications
    D. Batch audit
37. Based on FDA guideline for process validation; for which types of drugs concurrent validation release may be considered appropriate during PPQ stage validation?
    A. Drugs that are medically urgent such as Ebola vaccines
    B. Drugs manufactured in coordination with the agency to alleviate a short supply
    C. Orphan drugs, or veterinary drugs for which there may be a limited demand or use
    D. Radiopharmaceuticals drugs with short half-lives or expiry dates
    E. All types of the drug mentioned above.
38. Mistakes made in filling in documentation
    A. Should be neatly covered by white correcting fluid.
    B. Should be completely covered over with a dark black pen.
    C. Should be crossed through with a single line and initialed or signed, dated, and if appropriate, the reason recorded.
    D. Should be reported to the supervisor at once.
39. Which one of the following must be in place supported by a general SOP or method validation protocol for each product?
    A. Procedure
    B. Document
    C. VMP
    D. All of above
40. Vendor's _______ must be kept on file with other data, and accessible for review for each raw material.
    A. History and background`
    B. Certificate of analysis
    C. Audit report
    D. Stability report

41. Which one of the following is **INCORRECT** for the process validation of products, which are transferred from one site to another or within the same site?
    - A. The number of validation batches could be reduced by the use of a bracketing
    - B. Existing product knowledge, including the content of the previous validation, should be available.
    - C. Different strengths, batch sizes and pack sizes/ container types may also use a bracketing approach if justified.
    - D. Bracketing could be justified for legacy products based on extensive process knowledge from the development stage in conjunction with an appropriate ongoing verification programme.
    - E. Bracketing could be justified for new products based on extensive process knowledge from the development stage in conjunction with an appropriate ongoing verification programme.
42. The purpose of sodium displacement in pharmaceutical water system is
    - A. To protect downstream equipment from the hard water.
    - B. To protect downstream equipment from the soft water.
    - C. To protect upstream equipment from the hard water.
    - D. To protect upstream equipment from the soft water.
43. Which of the following statement is **TRUE** about 'reproducibility'?
    - A. It is not necessary to carry out reproducibility if intermediate precision determined
    - B. It is a precision between two and more analysts within a given laboratory
    - C. It reflects the integrity and precision of data between different laboratories
    - D. All are true
    - E. A and C
44. There is no need for validation of the assay of the drug substance during dissolution if the assay method used for the drug substance in the FPP is the same as for the dissolution.

    A. True B. False
45. "Limit of detection" and "limit of quantitation" are tests to be included in the _______ for a test method validation.
    - A. Master validation plan
    - B. Standard test method
    - C. Validation protocol
    - D. Change control request

46. Which type of process validation is conducted after the process has been in use for some time?

A. Prospective validation

B. Concurrent validation

C. Retrospective validation

D. Revalidation

47. Which one hold **FALSE** for Grade A cleanroom requirement

A. Airlocks must be at the same grade in the at rest condition (viable and particulate)

B. Single entry and exit for each personnel and materials is required

C. To be maintained at a positive pressure to Grade B

D. Background for RABS or isolator

48. Which one of the following discrepancies shall be dealt with remedial actions?

A. Production or machine stoppages

B. Deviations

C. Product Recalls

D. Quarantine products

49. Filtration sterilization is mainly employed for which types of medicinal products?

A. Degraded by terminal sterilization

B. Degraded by aseptic sterilization

C. Degraded by gas sterilization

D. None of the Above

50. The URS should be used

A. As a point of reference throughout the validation life cycle.

B. When selecting the required item from an approved supplier

C. To verify suitability throughout the subsequent stages of qualification.

D. To verify, at a later stage, that the purchased and supplied system, utility or equipment is in accordance with the manufacturer's needs as specified.

E. All

51. Vitamins and antibiotics in powder form can be sterilized by?

A. Dry Heat

B. Moist Heat

C. Radiation

D. Depyrogenation

52. As part of the process validation life-cycle, what percentage or units of solid oral dosage batches should be conducted for production pilot-scale batches

A. At least 100,000-units where multiplication factor for the scale-up does not exceed 10.

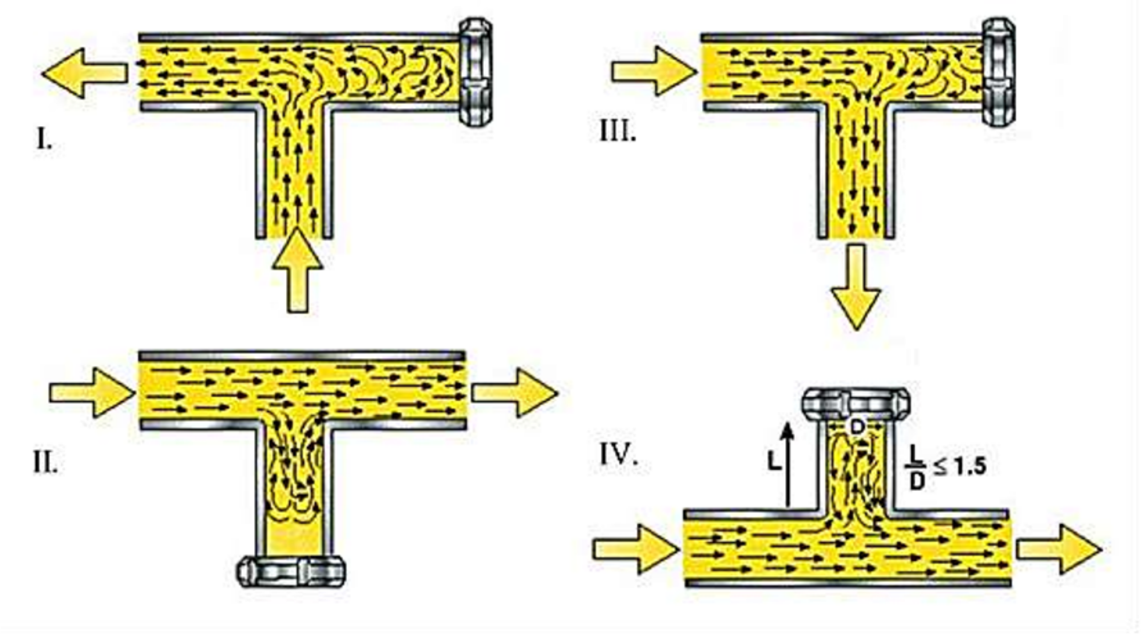
B. At least 0.10% or 1,000-units where multiplication factor for the scale-up does not exceed 10.

C. At least 10% where multiplication factor for the scale-up does not exceed 10.

D. At least 0.1% or 1,000-units where multiplication factor for the scale-up exceed 10.

E. A and C are the answers

53. Which one of the following is **FALSE** about qualification?
    - A. FAT and SAT usually are performed on large complex equipment not for all types of equipment's
    - B. FAT and SAT should be performed to verify the suitability of the system succeeding to the subsequent stages of qualification.
    - C. FAT and SAT are not mandatory, but they are clear regulatory expectation
    - D. FAT may be supplemented by the execution of a SAT following the receipt of equipment at the user site.
54. Which deadleg configuration design is believed to be recommended in order to minimize the formation of biofilms in water system?



A. I and II B. III and IV C. I and IV D. II and III

55. Spores and vegetative forms of microorganisms can be killed at 260°C within?

A. 30 Minutes B. 60 Minutes C. 45 Minutes D. None

56. Any change in the analytical method validation protocol must seek authorization by __.
    - A. Research and development
    - C. Quality control laboratory
    - B. Quality assurance
    - D. Production control
57. The appropriate implementation of QRM, does negate or circumvent manufacturer's obligation to comply with regulatory expectations including GMP.

A. True B. False

58. All of the following is **INCORRECT**
    - A. Instruments should be calibrated prior to OQ of the process or processing system.
    - B. IQ should include identification and verification of all system elements
    - C. Calibration and verification of equipment, instruments are initiated during installation qualification.
    - D. Prior to installation, equipment should be confirmed to comply with the URS and/or functional specification at the vendor site, if applicable
    - E. IQ is required to preceded DQ during the execution of qualification.
59. A written procedure needs to be available which prohibits making any changes except those _______ by QA.
    - A. Authorized B. Requested C. Prohibited D. Initiated
60. Which one hold **TRUE** for Grade C cleanroom requirement
    - A. Airlocks must be at the same grade in the at rest condition for viable and particulate
    - B. To be maintained at a positive pressure to Grade B
    - C. Any sinks or drains must be fitted with air breaks
    - D. Barrier from RABS or isolator
    - E. A and C
61. Which gas is used in solution form for sterilization of surgical instruments?
    - A. Ethylene Oxide C. Glutaraldehyde
    - B. Propylene Oxide D. BPL
62. Which processing activity of material in production should be given a new batch number.
    - A. Reprocessed B. Rework C. Recovered D. Blended
63. Which one of the following statements is/ are **TRUE** about annual product review?
    - A. The review timeframes can be adjusted based upon manufacturing and campaign duration
    - B. It should be conducted for stability, returns, complaints, and recalls even if there was no product manufacturing during the previous twelve-month period.
    - C. For campaign manufacturing, the review period can be extended beyond a year.
    - D. The product quality report should cross reference to the respective validation reports.
    - E. All
64. The sensitivity analytical performance increases with decreasing LOD and LOQ.
    - A. True B. False

65. In which cleanroom grade/s is disinfectants used may require to be sterile where determined in the CCS.

    A. Grade C and D B. Grade A and B C. Grade C D. Grade D

66. For sterile products, if the final formulation **CANNOT** be filtered, which one of the following factors should be considered during manufacturing to protect the product?

    A. Any product and component contact equipment should be sterilised prior to use.
    B. All raw materials or intermediates should be sterilised and aseptically added.
    C. Bulk solutions or intermediates should be sterilised
    D. All

67. Which one is used for the evaluation of the sterilization process?

    A. BIs B. Temperature C. Moisture Penetration D. All

68. All of the following is **INCORRECT** about PQ.

    A. PQ is often a stand-alone document as it requires longer testing time and a combination of equipment
    B. PQ shall be conducted under conditions that mimic routine operational procedures and shall as far as is reasonably practicable, include worst case conditions
    C. PQ can be appropriate to perform it in conjunction with OQ or Process validation
    D. PQ is required to be preceded by IQ and OQ and precedes process validation.
    E. None

69. Type of glass container commonly used for packaging pharmaceuticals and biologics?

    A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

70. Risk assessment is defined as

    A. A systematic process of organizing information to support a risk decision to be made within a risk management process.
    B. A systematic use of information to identify potential hazard source referring to the risk in question or problem description.
    C. It is expressed as qualitative or quantitative process of linking the likelihood of occurrence and severity.
    D. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
    E. A and B

71. All the parts of pharmaceutical equipment which are in direct contact with the product are preferably made of

    A. SS grade 304 B. SS grade 304L C. SS grade 316 D. SS grade 316L

72. If the analytical method is found to assess unequivocally the analyte in the presence of components that may be expected to be present, the method can be generally considered as;

    A. Specific B. Accurate C. Sensitive D. Linear

73. Unplanned changes are actually deviations and should be addressed using ______ procedures.

    A. Deviation handling C. Incidents handling

    B. Change control D. Validation

74. To which activities listed below does the ICH Q10 Pharmaceutical development is mainly implemented during development and manufacturing

    A. Drug substance and novel excipient development
    B. Formulation, delivery system and manufacturing process development including Container closure system
    C. Manufacturing of investigational drug products for clinical trials
    D. Scale-up and analytical method development
    E. All

75. The selection, qualification, approval and maintenance of suppliers of packaging materials shall be that given equal attention what is due for starting materials.

    A. True B. False

76. Which one of the following is/are **FALSE** for the process validation of product?

    A. The PPQ lots should be manufactured under normal conditions by different personnel from other operation to perform each step of each unit operation in the process.
    B. PPQ will have a higher level of sampling, additional testing, and greater scrutiny of process performance than would be typical of routine commercial production.
    C. The extent to which some materials, such as column resins or molecular filtration media, cannot be re-used even it does not adversely affect product quality
    D. The need for the level of scrutiny, testing, and sampling should be enhanced and continue to establish levels and frequency of routine sampling and monitoring for the particular product and process.
    E. A and C F. B and D

77. Which statement is **TRUE** about requalification outlined below
    - A. The scope and extent of requalification should be considered based on the outcome of risk management principles at defined intervals or as required as a result of investigations of deviations or complaints
    - B. DQ, IQ, OQ, and PQ are all part of major re-qualification stages to be considered.
    - C. Major and minor requalification include complete or portions of the elements of qualification.
    - D. Analytical instrument minor repair requalification, OQ and PQ are recommended
    - E. All except B
78. During manufacturing, which type of cleaning is performed when we move from higher dose(strength) to a lower dose of the same product in pharmaceutical industries?
    - A. Type A cleaning
    - C. Type B cleaning
    - B. Type C cleaning
    - D. None of the above
79. During in operation, tablet manufacturing area maintains
    - A. Class A
    - B. Class B
    - C. Class C
    - D. Non-classified
80. The ICH Q7A concept of validation for the manufacture of medicinal products and API.
    - A. For medicinal products all manufacturing steps need to be validated, whereas for APIs only, critical processing steps that have impact on its quality and purity need to be validated.
    - B. Equally for medicinal products and API only, critical processing steps that have been assessed as impacting the quality need to be validated.
    - C. For APIs all manufacturing steps need to be validated, whereas for medicinal products only those critical process steps that have impact on product quality need to be validated.
    - D. None
81. The review input and comments along with any ____________ should be included on the form and attach with the finished product reports.
    - A. Recommendations
    - C. Corrective action
    - B. Change in process
    - D. Change in specification
82. In bubble air-lock system, on the door opening air moves from
    - A. Airlock to the primary area
    - C. Primary area to air-lock
    - B. Corridor to air-lock
    - D. None

83. Which one is an advanced type of sterilization?

A. UHP   B. HILP   C. Gas Plasma   D. All

84. Which one of the following statements is/ are **TRUE** about annual product quality review?

A. PQR should normally be conducted annually and only for sterile products
B. There is no need to included changes to the analytical methods in the PQR
C. There is no need to prepare a PQR when less than 5 batches have been manufactured
D. The evaluation and conclusion of the PQR have to be approved by the inspectors.
E. The objective of PQR is to assess the consistency of the manufacturing process

85. Which type of HVAC is more efficient compared to others in pharmaceuticals?

A. Dx type   B. Chilled water   C. SAD   D. RAD

86. Which of the following is/are the prerequisite to achieve reliably the quality objectives of PQS?

A. A well-designed and appropriately implemented QMS, that incorporates both GMP and QRM
B. The PQS should be fully documented and monitor its effectiveness at the level of manufacturing site
C. Determining all the inputs pertaining to the quality system should adequately resourced with competent and qualified personnel, premises, equipment and facilities required.
D. There should be legal responsibilities in place for the holder of the MA and Qualified Person(s).
E. All

87. The analyst's ability to properly gown in sterile area should be evaluated by means of

A. Contact plate   B. Surface plate   C. RODAC   D. Media fill

88. When to validate/qualify an instrument?

A. Before introduction of a new method into routine use.
B. Whenever the conditions change for which a method has been validated,
C. Whenever the method is changed, and the change is outside the original scope of the method.
D. Validation is a constant, evolving process starting before an instrument is placed on-line, and continues long after method development and transfer.
E. All

89. Which is **TRUE** about the method validation with respect to linearity
    - A. Linearity is required for Assays and Quantitative
    - B. Linearity may be required for performance tests of dissolution
    - C. Linearity is not required for Limit tests and Identification
    - D. All
90. In using approved materials from storage using FEFO approach the drug product's shelf life must not exceed the shelf life of the APIs
    - A. True
    - B. False
91. **WRONG** about the results of the validation summary reports (VSR)
    - A. Recorded in compliance with good data and record management practices.
    - B. Reviewed, analyzed and compared against the predetermined acceptance criteria, interpreted and statistically analyzed
    - C. Results which fail/pass to meet the pre-defined acceptance criteria should be recorded as a deviation
    - D. Results which fail/pass to meet the pre-defined acceptance criteria should be recorded as OOS
    - E. Any implications for the validation should be discussed in the report.
92. Changes in laboratory analytical methods may impact product quality and _______.
    - A. Product release criteria
    - B. Product specifications
    - C. Regulatory commitments
    - D. Product stability
93. Which one of the following are/is **TRUE** about validation?
    - A. Validation ensures the product quality and reduces the chances of non-compliance and product recall.
    - B. During inspection validation data gives assurance to the inspecting bodies that the procedures are reliable and acts as proof in making decisions.
    - C. Meet regulatory requirements.
    - D. Once the product is validated, cost of manufacturing is reduced which in turn leads to less testing.
    - E. All
94. Which one is used for the sterilization of plastic and paper board?
    - A. Moist Heat
    - B. Dry Heat
    - C. EtO Gas
    - D. Filtration

95. Which one hold **FALSE** for Grade B cleanroom requirement
    A. Airlocks must be at the same grade in the at rest condition
    B. Separate entry and exit for personnel and materials is required
    C. To be maintained at a positive pressure to Grade C
    D. Background for Isolator
96. Which cleanroom class should be maintained for the manufacturing oral liquid at rest?
    A. Class A B. Class D C. Class B D. Class C
97. In HVAC system, the mixing box is present in
    A. Supply air duct C. Return air duct
    B. Air handling Unit D. Damper
98. Type C cleaning in pharmaceutical industries is also known as
    A. Product changeover cleaning C. Same product cleaning
    B. Shift end cleaning D. All of the above
99. Risk identification
    A. A systematic use of information to identify potential hazard source referring to the risk in question or problem description.
    B. The estimation of the risk associated with the identified sources hazards.
    C. It is expressed as qualitative or quantitative process of linking the probability of occurrence and severity that harm.
    D. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
    E. B and D
100. Dead legs in water loop circulation system can be prevented by maintaining the velocity of purified water at
    A. 1.0-2.0 m/sec B. 2.0-3.0 m/sec C. 2.5-3.5 m/sec D. 0.5-1.0 m/sec
101. In which phase of the process validation do we expect the critical steps and critical process parameters should be identified, justified, and documented.
    A. Process development C. PAT
    B. Process performance qualification D. Continued process verification
102. How is moisture typically measured in freeze-dried products?
    A. Karl Fischer B. Pirani gauge C. Thermocouples D. Pressure rise test

103. Which one of the following is **FALSE** about action level and alert level in pharmaceutical water system?
   - A. None of the limits for water are pass/fail limits. All limits are action limits.
   - B. Alert levels should be set based on data gathered during phase one initial qualification stage of water system.
   - C. Exceeding alert level is critical deviation and do not necessarily require corrective actions and need to be recorded in BMR
   - D. Exceeding action level indicates that the process has allowed the product CQA or CPP to drift outside of its normal operating range.
104. A QC lab is using single login & password for HPLC to control the cost of licenses & utilizes a logbook to record run data & analyst details
   A. Attributable B. Legible C. Contemporaneous D. Accurate
105. The minimum quality source for sterile water for injection as defined by EU, WHO is
   A. Drinking water B. WFI C. PW D. A and B
106. What is a worst-case scenario in cleaning validation terms? A scenario in which,
   - A. The highest amount of residue is expected to remain on equipment after cleaning
   - B. The lowest amount of residue is expected to remain on equipment after cleaning
   - C. No residue is expected to remain on equipment or surfaces after cleaning
   - D. The cleaning procedure is expected to be most effective
107. All changes in test methods are governed by a _________ according to which the proposals, evaluation and implementation of changes could be controlled.
   A. Method B. System C. Person D. Protocol
108. The decision and justification to be made for the number of process runs for process validation should be based on
   - A. The complexity of the process
   - B. The expected variability of the process
   - C. The magnitude of the process change being considered
   - D. The critical quality attributes (CQAs).
   - E. All
109. As per the USP, the aerobic bacterial limit for PW is 3 logs higher than the WFI specification
   A. True B. False

110. Turbulent flow occurs at which Reynold Number?

A. > 1000 B. > 2000 C. > 3000 D. > 4000

111. In case QC lab has a reduced testing program in place then a _______ is required to be available to describe as to when reduced testing can be instituted.

A. Standard operating procedure C. Validation protocol

B. Master plan D. Quality assurance approval

112. Procedure for dismantling and reassembling of equipment where necessary to assure proper cleaning, must be part of ____________.

A. Equipment master validation plan C. Maintenance and preventive SOP

B. Cleaning and sanitization SOP D. Calibration plan

113. Conclusion of the validation summary reports (VSR) should state

A. Regardless of the result as fail/pass, make recommendations for future monitoring and setting of alert and action limits,

B. Results should be summarised against the pre-defined acceptance criteria.

C. Any subsequent changes to pre-defined acceptance criteria should be scientifically justified

D. Final recommendation should be made as to whether or not the outcome was considered successful validation

E. All are included in the validation summary reports

F. B and C

114. In operation syrup manufacturing takes place

A. Class A B. Class B C. Class C D. Class D

115. During aseptic manufacturing which one of the following is **FALSE** for vial capping undertaken as a clean process outside the aseptic core?

A. Vials should be protected by Grade A conditions up to the point of leaving the aseptic processing area

B. Stoppered vials should be protected with Grade A air supply until the cap has been crimped.

C. Grade A air supply should meet at least grade D background requirements.

D. Vials with missing or displaced stoppers should be rejected prior to capping.

E. All are true statement

116. Change control is a ____________ of reviewing and analyzing the effect of a change and to ensure that system retains its validated status.

A. Process B. License C. Monitoring system D. Sign

117. OOS results can arise from cause, which can be divided into three categories: laboratory error, process-related error, and ____________.

A. Non-robust method C. Non-process-related error

B. Analyst error D. Equipment failure

118. Bag filters of HVAC are also called

A. Coarse Filters B. Fine Filters C. Ultra-pure filters D. All

119. What method is used to verify that the sterilizer air removal mechanism is functioning properly?

A. Dynamic air removal test C. Sterilizer indicator tape

B. Bacterial spore strip D. None

120. Any lot of finished product released by concurrent validation during PPQ

A. Must comply with all cGMPs

B. Must require regulatory approval requirements

C. Should be fully described in the PPQ protocol for its specification and release criteria.

D. Lot is released before the entire study protocol has been executed.

E. All

121. The retention samples must be of ____________ the quantity necessary for all tests required to determine that the active ingredient meets its established specifications.

A. 3x B. Similar C. 2x D. Lesser

122. Which one holds **TRUE** for Grade A cleanroom requirement

A. Airlocks must be at the same grade in the at rest condition (viable and particulate)

B. Separate entry and exit for personnel and materials is required

C. To be maintained at a positive pressure to Grade B (minimum 10 Pascals).

D. Barrier from RABS or isolator

E. A and D

123. DOP test for ISO class 5 or Grade A should be carried out after

A. 3 Months C. 6 Months

B. 9 Months D.12 Months

124. Risk analysis is defined as

A. The estimation of the risk associated with the identified sources hazards.

B. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.

C. It includes actions taken to mitigate the severity, increase detectability, and reduce probability of harm. Thus; the identified risk can be reduced by

D. It is expressed as qualitative or quantitative process of linking the likelihood of occurrence and severity.

E. A and D

125. Which of the following ICH guidelines addresses the residual solvents?

A. ICH Q2(R1) B. ICH Q3B C. ICH Q3C D. ICH Q3D

126. Finished products should be physically and administratively quarantined immediately after processing, until they have been released for distribution.

A. True B. False

127. The experimental approach of process validation, which is applicable to both prospective and concurrent validation, may **NOT** involve

A. Extensive product testing C. Simulation process trials

B. Challenge/worst case trails D. Control of process parameters

128. Which one of the following are/is **INCORRECT** about validation?

A. Validation studies verify the system under test (under the extremes expected) during the process to prove that the system remains in control.

B. Once the system or process has been validated, it is expected that it remains in control, provided no changes are made.

C. In the event that modifications are made, or problems occur, or equipment is replaced or relocated, revalidation is not performed.

D. Non-critical equipment and processes are routinely revalidated at appropriate intervals to demonstrate that the process remains in control.

E. C and D

129. The Bowie Dick test is now known as the

A. Dynamic air removal test C. Air challenge test

B. Process challenge test D. Diagnostic test

130. Which one is **NOT** element of ICH Q10 Pharmaceutical quality system?

A. Process Performance and Product Quality Monitoring System
B. Corrective Action and Preventive Action (CAPA) system
C. Attain and Maintain a state of control
D. Change Management System
E. Management Review

131. HEPA filters used in HVAC are also known as

A. Coarse Filters B. Aerosol filters C. Fine Filters D. All

132. Where are test packs placed to present the greatest challenge to the steam sterilizer?

A. Bottom rack back C. Top rack back
B. Center D. Over the drain

133. The sterilizer heat sensing thermometer is located in the

A. Chamber B Jacket C. Drain line D. None

134. Risk evaluation is defined as

A. A systematic use of information to identify potential hazard source referring to the risk in question or problem description.
B. It considers the strength of evidence for all three of the fundamental questions (probability, severity and detectability)
C. It is expressed as qualitative or quantitative process of linking the probability of occurrence and severity that harm.
D. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
E. B and D

135. A clean corridor concept is usually recommended for non-sterile oral solid-dosage form production areas, where there is then a higher pressure in the corridor compared to airlocks or production rooms.

A. True B. False

136. The general SOP for IQ, OQ, and PQ must also describe in detail the requirement of ____________ prior to commencing the qualification process.

A. Master plan C. Approved protocol
B. GMP guidelines D. Permission of QA

137. Which one of the following is **INCORRECT** about deviation and its management?
   - A. Treating unplanned deviation as a deviation is cGMP compliant since deviation is an unexpected event.
   - B. Planned deviation is not a substitute for a change management process and should be approved by QA before implementation.
   - C. QRM is mainly designed to be used retrospectively when manufacturing operations are defined and validated.
   - D. Treating a planned deviation as a deviation is not cGMP compliant rather it is treated as temporary change management.
   - E. Any planned changes or deviations in manufacturing or QC should be notified in accordance with a well-defined reporting system before any product is released.
138. The three parameters of steam sterilization are
   - A. Pressure, time, and temperature
   - C. Time, temperature, and concentration
   - B. Temperature, time, and humidity
   - D. A and B
139. Types of airlocks system design for clean rooms in pharmaceutical industries are
   - A. Bubble airlock
   - C. Sink airlock
   - B. Cascade airlock
   - D. All
140. The classification of residual solvents in three classes is based on
   - A. The solvent's relative volatility
   - C. Difficulty of their removal from the product
   - B. The solvent's risk to human health
   - D. All of the above
141. Which method of sterilization is used to sterilize liquids?
   - A. Ethylene oxide B. Peracetic acid C. Prevac steam D. Gravity steam
142. Which of the following is corrective action?
   - A. Replacing the label on a device that had the wrong label applied
   - B. Revising process parameters in response to complaints
   - C. Rewelding a contact that does not meet visual inspection requirements
   - D. Auditing all vendors of a key component after quality issues with only one vendor are identified
   - E. A and C
143. Which type of glass container is suitable for storing light-sensitive substances?
   - A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

144. What are the typical activities need to be accomplished during product discontinuation
    - A. Managing effectively any changes after ceasing product manufacturing should go through an appropriate change management system.
    - B. Retention of documents and samples of products which were commercially available
    - C. Monitoring continuously the product stability that are available on the market though its manufacturing has been ceased until completion of its study.
    - D. Review of management for reporting and compliant handling as per regulatory requirement
    - E. All
145. How is secondary drying shelf temperature determined in lyophilization process?
    - A. Residual moisture of the product
    - B. Vapor pressure of the product
    - C. Thermal stability of the product
    - D. Pirani gauge reading
146. Which feature of Closed isolator makes it different form open isolator's
    - A. Maintain Grade A conditions and ensure first air
    - B. Air does not need to be unidirectional, but the risk of turbulent air must be understood
    - C. Be subject to leak / integrity testing
    - D. Gloves must be examined before and after each use
    - E. Gloves must be integrity tested at the start and end of each campaign or more often
147. The dynamic air removal test is considered which type of monitoring process?
    - A. Chemical
    - B. Mechanical
    - C. Biological
    - D. All
148. Which one is the correct sterilizer setting for the dynamic air removal test?
    - A. 3.5-4min at 270°F or 134°C. Gravity
    - B. 2-4 at 250°F or 121°C. Gravity
    - C. 3.5-4min at 270°F or 134°C. Prevac
    - D. 2-4 at 250° F or 121°C. Prevac
149. What are the decisions and actions of outcomes of annual product review should typically address to keep the process and other parameters in a state of control.
    - A. By highlighted trend analysis determine for there is a need for validation and/or revalidation of the process or manufacturing
    - B. Clearly defined CAPA and recommendations whether modifications to product specifications, manufacturing instructions or control procedures are required.
    - C. Implementing process changes using appropriate change control procedure
    - D. All

150. According to ISO 11140; Type 5 chemical indicator is called?

A. Integrator C. Process indicator
B. Emulator D. Special

151. **INCORRECT** features about open isolators

A. Maintain Grade A conditions and ensure first air
B. Ensure unidirectional airflow, capable of sweeping away contamination
C. Located in a Grade C cleanroom (minimum)
D. Airflow visualisation must focus on closed area interfaces

152. The minimum quality source for water for hemodialysis as defined by the EU, WHO is

A. Drinking water C. Water for Injection
B. Purified water D. A and B

153. The risk specific to sterile injectable products is

A. Purity B. Identity C. Sterility D. pH

154. At the time of commercial manufacturing a continued or ongoing data acquisition are gathered to establish a commercial manufacturing process capable of consistently producing a product with its intended quality. **EXCEPT**

A. QA, QC and environmental monitoring,
B. Statistical analysis of Cpk, Ppk
C. Storage of products including wholesalers
D. Critical process failures, audits, investigations, and OOS results
E. Acquisition, controls, distribution and release of materials
F. Provision of facilities, utilities and equipment

155. As per EU GMP Annex 1, microbiological active air action levels for Grade C is

A. 100 CFU/m^3 B. 1 CFU/m^3 C.10 CFU/m^3 D. 200 CFU/m^3

156. The cleaning and disinfection procedures must be ___ for their effectiveness on specific surfaces and on specific organisms as well as their recovery studies from surfaces.

A. Validated B. Checked C. Reviewed D. Guaranteed

157. During which stage of the process validation; methods for product release and stability should be fully validated according to ICH requirements prior to initiating it.

A. Process design C. Pilot scale up manufacturing
B. Process performance qualification D. Continued process verification

158. What does the EU Annex 1 Sterile manufacturing aim to prevent in the final product?

A. Microbial contamination

B. Particulate contamination

C. Endotoxin/pyrogen contamination

D. All of the above

159. Which one of the following is **NOT TRUE** about stability study according to WHO?

A. A means to investigate how a medicine behaves under different environmental conditions

B. Demonstrate that a product maintains its fitness for use throughout this labeled shelf life.

C. Underpins the whole lifecycle for a pharmaceutical product,

D. No intermediate storage condition is recommended for Zones III and IV.

E. For stability studies, common practice is to use an expiration date.

160. In vertical laminar flow cabinet, air leave the working area via

A. HEPA filter

C. Holes from the top grills

B. Holes in the base via ducts

D. None of these

161. Which one is a wet sterilization system for unwrapped items?

A. Peracetic acid B. VHP C. Ethylene oxide D. Ozone

162. Quality management is defined as the aspect of management function that determines and implements the quality policy.

A. True B. False

163. The destruction of microorganisms by moist heat is described by ____

A. Zero-order reaction

C. First-order reaction

B. Third-order reaction

D. Second-order reaction

164. What is the advantage of batch sterilization over continuous sterilization?

A. Superior maintenance of quality

C. Ease of scale-up

B. Automatic control

D. Lower equipment cost

165. Residual solvents are defined as

A. Organic volatile chemicals used in the manufacturing process.

B. Organic volatile chemicals produced during the manufacturing process.

C. Organic volatiles used or produced in the manufacturing that are not removed during purification.

D. All

166. According to WHO, 2021 WFP use, the surface roughness for sampling valves typically installed between process stages and on the return valve of distribution loop for PW and WFI systems should be

   A. Ra ≤ 1.0 microns C. Ra ≤ 0.8 microns
   B. Ra ≤ 0.1 microns D. Ra ≤ 0.6 microns.

167. Which water for injection requirement is **FALSE**

   A. Produced by distillation
   B. Maintained in a sanitary state at a temperature >70°C
   C. Filter controls in place for tanks (integrity testing and condensation avoidance)
   D. Periodic TOC and conductivity monitoring must be in place
   E. None of the above

168. Risk reduction is defined as

   A. It focuses on processes for mitigation or avoidance of impact on quality risk when it exceeds a specified (acceptable) level.
   B. It includes actions taken to mitigate the severity, increase detectability, and reduce probability of harm.
   C. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
   D. Monitoring of output or results of the risk management process considering (if appropriate) new knowledge and experience about the risk.
   E. A and B

169. Type of laminar flow hoods used for protection from fumes and gases

   A. Class-I B. Class-II C. Class-III D. Class-IV

170. **INCORRECT** statement about process validation

   A. Process parameters such as variables controlled to minimize energy consumption or equipment use, need not be included in the process validation.
   B. There is no need for revalidation where significant changes have been made to the system or process,
   C. There is no need for revalidation where a quality review confirms that the system or process is consistently producing material meeting its specifications,
   D. Process validation is to be preceded by process performance qualification.

171. Routine BI testing for steam sterilizers should be performed at least

   A. Daily B. Weekly C. Every other day D. Monthly

172. The moist heat is more effective than the dry heat because the intrinsic heat resistance of vegetative cells is greatly

   A. Increased in a dry state C. Decreased in a dry state

   B. Increased in a wet state D. Decreased in a wet state

173. Parenteral preparations can be sterilized through?

   A. Chemical sterilization C. Membrane filtration

   B. Desiccation D. Dry heat method

174. The entry of the contaminants can be avoided

   A. By using a sterile inoculum

   B. By sterilizing the medium and other medium components

   C. By sterilizing the fermenter vessel and other ancillary equipment

   D. All of the above

175. HEPA filter has pore size of

   A. 0.1-micron B. 0.3-micron C. 0.5-micron D. None

176. In sterilization process, spore of which organism is considered as control?

   A. Bacillus subtilis C. Clostridium botulinum

   B. Bacillus stearothermophilus D. Aspergillus niger

177. Basic principle behind sterility testing is?

   A. Microorganisms imparts different colors when present as contaminant in any preparation

   B. Presence of microbes can be detected by naked eye in any preparation

   C. Microbes will grow if they will be provided with nutrient medium, optimum temperature and pH

   D. None of the above

178. The following should be considered during aseptic process validation

   A. Line speed and configuration C. Shift change and change over

   B. Aseptic connection and disconnection D. Personnel and their activities

179. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification; indeed, this shall be seen as a continuum.

   A. True B. False

180. Risk analysis is a systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the evaluation of risk associated with exposure to those hazards.

A. True
B. False

181. As per EU GMP Annex 1, the maximum number of particles/m^3 of ≥ 5-µm size at rest in Grade A area is

A. 29
B. 2,930
C. 293
D. 29,300

182. The vertical air velocity at working level in Grade A area,

A. Should be NLT 0.55 m/s
B. Should be NLT 0.45 m/s
C. Should be NLT 0.36 m/s
D. None of the above

183. Which one comes under physical method of sterilization?

I. Moist heat method
II. Oxidation
III. Sunlight
IV. Osmotic pressure
V. Lyophilization
VI. Ethylene oxide treatment

A. III, IV, VI
B. I, III, IV, V
C. I, V
D. II, IV, VI

184. The classification of area required for filling of solutions of terminally sterilized products when unusually (abnormal) at risk

A. Grade A with grade C background
B. Grade C with grade D background
C. Grade A with grade D background
D. Grade A with grade B background

185. GMP is primarily aimed at

A. Diminishing the risk inherent in production
B. Ensuring products are consistently produced and controlled
C. Diminishing risk that cannot be controlled by testing of product
D. A and C

186. How do we evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere?

A. By reviewing and analysing the nonconformity
B. By determining the causes of the nonconformity
C. By determining if similar nonconformities exist, or could potentially occur
D. A and B
E. All

187. Which of the following statements is/are **CORRECT** about biological indicators?
   A. Bacillus subtilis var. niger is used to monitor the process of radiation sterilization.
   B. Bacillus atrophaeus is used to monitor the process of dry heat sterilization.
   C. Geobacillus stearothermophilus is used to monitor the process of steam sterilization.
   D. Bacillus pumilus is used to monitor the process of dry heat sterilization.
   E. Geobacillus stearothermophilus is used to monitor the process of radiation sterilization.
188. Which one filters are used in HVAC?
   A. Carbon filter B. Bag filters C. Sand filter D. None
189. For classification purposes in Grade A area, a minimum sample volume of
   A. 1 m^3 per sample location C. 0.1 m^3 per sample location
   B. 0.01 m^3 per sample location D. Sampling is no longer applicable
190. Risk evaluation is the final step of typical risk assessment process. The other two steps are risk analysis and risk reduction
   A. True B. False
191. Changes that may require revalidation
   A. Change of site and/or production area
   B. Change of source of the biological starting material
   C. Change in a process step
   D. Significant change in a critical equipment
192. When steam comes into contact with injectable products in its final container, or equipment for preparing injectable products, it should conform with the specification
   A. For WFI when condensed C. For sterile WFI when condensed
   B. Purified Water when condensed D. Highly purified water when condensed
193. Generally, which stage of the process validation do not need to be performed under the cGMP-compliant procedures conditions rather needs to be conducted in accordance with sound scientific methods and principles, including GDocP consistent with ICH Q10
   A. Process design C. Pilot scale up manufacturing
   B. Process performance qualification D. Continued process verification
194. Turbulent air flow blowing from AHU cleans a classified/controlled area by
   A. Displacement of dirty air C. Dilution of dirty air
   B. None of the above D. None

195. What is the final step in the lyophilization process?

A. Adding a stabilizing agent	C. Backfill and Stoppering the product
B. Sterilizing the product	D. Removal of dried product from freeze dryer

196. According to FDA the recommendation for air velocity inside aseptic room is

A. 100 ft/min ± 10%	C. 90 ft/sec ± 20%
B. 90 ft/min ± 20%	D. 200 ft/min ± 20%

197. Which of the following statements is **CORRECT** about autoclaves?

A. They use dry heat to kill bacterial endospores.
B. They are good at removing pyrogens from glass.
C. They operate below atmospheric pressure.
D. They use saturated steam to kill microorganisms.
E. Gravity displacement systems are suitable for porous loads.

198. Which of the following statements is **CORRECT** about biological indicators?

A. Biological indicators normally contain vegetative bacteria, of concentration not less than 106 CFU mL^{-1}.
B. Biological indicators must be nonpathogenic.
C. Biological indicators are used to ensure that the physical conditions in a sterilizer have been met.
D. Biological indicators are not particularly resistant to a sterilization process.
E. Biological indicators must be used every time a sterilizer is used.

199. When testing a batch of products for sterility:

A. Only products from the hottest part of the autoclave should be tested
B. A successful test proves that a batch is sterile
C. Neutralization of antimicrobial activity may be required
D. An isolator and/or clean room is not required
E. Controls are not needed as long as the product passes at the first attempt

200. Which of the following is **NOT** a limitation of gamma irradiation?

A. Thermal degradation of containers
B. Butyl and chlorinated rubber are degraded
C. Hardness and brittleness properties of metals may change
D. Liberation of gases

201. The risk assessment associated with the identified hazards involves
   A. Risk review B. Risk analysis C. Risk control D. Risk Identification
202. Height of partition between two packaging lines should be
   A. 1-meter B. 2-meter C. 1 feet D. 2 feet
203. As control measures for assurance of sterility,
   A. The sterility test is the only control measure
   B. The sterility test is the last in series of control measures
   C. The sterility test is the first control measures
   D. None of the above
204. During aseptic simulation study
   A. Ideally no contaminated should be detected
   B. A contaminated unit may be detected and acceptable but depends on batch size
   C. If a contaminated unit is detected, an investigation should be carried out always
   D. If a contaminated unit is detected, an investigation and revalidation should be carried
205. Which one is a preventive action in the CAPA process?
   A. Replacing a defective product C. Training employees
   B. Issuing a recall for a faulty product D. Compensating for a product defect
206. Dead legs in the pipework in water systems
   A. Should not significantly exceed three times the branch diameter as measured from the ID pipe wall to center line of the point-of-use valve.
   B. Should be less than six times the branch diameter as measured from the ID pipe wall to center line of the point-of-use valve.
   C. Should always be zero dead leg.
   D. None of the above.
207. Which one of the following is **CORRECT** about deviation and its management?
   A. Repetitions incident can't turn it into a minor deviation and minor to major.
   B. Incident and minor deviations do not necessarily require an investigation aimed at identifying the root causes of the problem
   C. Major and critical deviations necessarily require an investigation aimed at identifying the root causes of the problem
   D. Minor deviations are normally addressed root cause analysis and CAPA

208. Identify the risks specific to sterile injectable products
A. Purity B. Sterility C. Identity D. Unacceptable endotoxins level

209. The compendial requirements for the content of Class II solvents are met by
A. Meeting the concentration acceptance criteria entered in the chapter for doses not to exceed 10 grams
B. Ensuring that the daily exposure to the solvent is not more than the PDE
C. Either meeting the concentration acceptance criteria for doses exceed 10 grams
D. Either using method A or B

210. As per the current WHO guideline, the viable count in grade A area should be
A. NMT 5 CFU per location C. < 2 CFU per location
B. No growth of any CFU per location D. None of the above

211. The microbiological limit of water for injection is
A. 500 CFU/ml B. < 100 CFU/ml C. < 10 CFU/100 ml D. 100 CFU/10 ml

212. Growth of microorganisms in water system can be reduced by
A. Ultraviolet radiation sources in pipe work
B. Sanitizing the system periodically using hot water of temperature >70ºC
C. Sterilizing or sanitizing the system periodically using clean steam
D. Routine chemical sanitization using ozone
E. All are answers

213. Which of the following is **NOT** an example of a live attenuated vaccine?
A. Tetanus vaccine C. MMR vaccine
B. Varicella (chickenpox) vaccine D. Influenza vaccine

214. Sampling plan should also include sample size and ____________ in case of powders, granules, and liquids.
A. Name of sampler C. Sample locations
B. Type of tests to be done D. Name of process

215. Which one is a disadvantage of lyophilization?
A. Longer production time compared to other methods
B. Higher cost compared to other methods
C. Limited applicability to certain types of products
D. All of the above

216. The objective of Product quality review is to verify the consistency of the existing process including the appropriateness of current specifications for both starting materials and finished product and to identify the need for product or process improvements.

A. True B. False

217. Preconditioning of the sterilizer load is done by

A. Running the sterilizer for 1 min and then restarting the load
B. Placing the load in the sterilizer and closing the door for 15 minutes
C. Letting the load come to room temperature and then starting the cycle
D. None

218. Risk review

A. Where CAPA effectiveness is explored to monitor the specific risk control measure relative to its acceptance limits
B. The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk.
C. Monitoring of output or results of the risk management process considering (if appropriate) new knowledge and experience about the risk.
D. A and C

219. How often should HEPA filters be tested for leaks?

A. Monthly B. Every 3 months C. Every 6 months D. Every year

220. Trend analysis

A. Allows inspectors to review plotted aggregated data overtime.
B. Can be extremely valuable as an early warning indicator of potential problem.
C. Is based on the idea that what has happened in the past gives an idea of what could happen in the future.
D. All

221. The sterility of the terminally sterilized load is always assured by validation of the sterilization cycle.

A. True B. False

222. What type of sampling method is typically used for worst case cleaning validation?

A. Random sampling C. Swab sampling
B. Rinse sampling D. Visual inspection

223. Which one is **NOT** a factor that can impact the effectiveness of SIP?
    A. Cleaning agent concentration and contact time
    B. Sterilization time and temperature
    C. Equipment design and configuration
    D. Humidity levels in the sterilization chamber

224. Which of the following is **NOT** a component of downstream processing?
    A. Expression B. Preservation C. Purification D. Separation

225. What are some common aseptic techniques used in pharmaceutical manufacturing?
    A. Laminar flow hoods, clean rooms, and sterile barriers.
    B. Gloves, masks, and gowns.
    C. UV lights, hydrogen peroxide vaporizers, and ozone generators.
    D. None of the above.

226. Which phase of the process validation studies should form the basis for process optimization, process validation and continuous process verification
    A. Process development
    C. PAT
    B. Process performance qualification
    D. Continued process verification

227. GMP deficiencies
    A. Should be classified based on the assessed risk level and may vary depending on the nature of the products manufactured.
    B. If comprehensives, do not need to be referenced in the inspection report to the relevant GMP requirement, who guidelines or conditions or commitments under the marketing authorization.
    C. Are findings or statements of fact made during an inspection and substantiated by objective evidence.
    D. A and C

228. Which of the following defines the principle of first air?
    A. Performing aseptic manipulations at least 6 inches inside the workbench
    B. Certifying the LAFW every six months
    C. Allowing sterile 70% isopropyl alcohol to dry before compounding
    D. Keeping the airflow between the HEPA filter and the sterile object unobstructed
    E. If turned off, operate LAFW for 30 minutes before use to purge room air

229. What type of cleaning is expected to be performed during Minor preventive maintenance in which parts in direct contact with the product are not exposed.

A. Type A B. Type B C. Type C D. A and C

230. Which steam quality requirement is **FALSE**

A. The steam must be free of additives
B. Microbial test requirements are a must
C. Testing must be regular
D. Testing chemical purity, non-condensable gases, dryness value and superheat

231. All retention samples of active materials are to be retained for ____________ after expiry of the last lot of the product containing the material.

A. Two years B. Six months C. Five years D. Once a year

232. What is the critical point of water?

A. 374°C B. 157.5°C C. 31.0°C D. 240.9°C

233. The changes that may affect _____ should be managed in accordance with change control procedure.

I. Production cost II. Product quality III. Process reproducibility

A. I and III B. II and III C. III only D. I, II and III

234. A well performed and documented PQR is a good justification to test partially the starting materials used for the production of vaccines.

A. True B. False

235. Risk based inspection should…

A. Identify all systems that impact the high-risk processes.
B. Identify high risk steps within the critical systems.
C. Identify as minor risk, the major or sole supplier of an essential product.
D. All above.

236. Validation of LOD and LOQ are **NOT** required for which one of the following

A. Assay and Identification C. Assay and limit test
B. Limit test and quantitative limit test D. Assay and dissolution

237. In case no changes occur regarding the manufacturing facility and process, the aseptic process is generally recommended to be revalidated at least twice a year.

A. True B. False

238. Manufacturing of sterile products which require terminal sterilization takes place in

A. Class A B. Class B C. Class C D. Class D

239. Which of the following statement is Incorrect about the vaccine development process?

A. A vaccine consists of live attenuated or killed germ cells
B. Aluminum can be used as an adjuvant in a vaccine
C. Animal trials are not necessary for vaccines before going to the human trial
D. An effective and safe vaccine production can take up to 10 to 15 years

240. When should be annual product quality review be conduct for statistically invalid a small number of batches of a product that have been manufactured during the review period?

A. Every other year B. Every year C. Twice years D. At any year

241. What occurs if vacuum control is lost and pressure rises?

A. Product temperature rises C. Product temperature decreases
B. Shelf temperature rises D. Shelf temperature decreases

242. Its goal is to propose a process suitable for routine commercial manufacturing that could consistently deliver a product that meets its quality attributes.

A. Process Design C. PAT
B. Process performance qualification D. Continued process verification

243. What is the purpose of a risk assessment in a pharmaceutical quality system?

A. To identify potential hazards and risks associated with products and processes
B. To determine the cost of implementing corrective actions
C. To evaluate employee performance
D. None of the above

244. Inspection report should be written in active voice instead of passive voice.

A. True B. False

245. Movement of items from lower grade or unclassified area to higher grade clean areas

A. Should be subject to cleaning and disinfection commensurate with the level of the risk
B. Should be biodecontaminated to a level of cleanliness at least equivalent to the environment the items are entering.
C. Should be should be in the same cleanliness grade as the cleanroom into which it leads.
D. A and B
E. All are correct answers.

246. Which one is **CORRECT** for the concept of deviation?
    - A. It is failure to meet a requirement in approved procedures.
    - B. QA manager can release a product before the assessment of a deviation is completed.
    - C. There should be procedures to report, investigate and approve deviation.
    - D. A and C
247. Which one of the following is **CORRECT** about Risk control?
    - A. Decisions need to be made as to the acceptability of the risks as they exist or if actions need to be taken to reduce risks.
    - B. The purpose of risk control is to reduce the risk to an acceptable level.
    - C. The focus will be on the higher-level risks with the efforts to reduce proportionate to the potential risk
    - D. A and C
    - E. All are true statements regarding risk control
248. To keep a better control over the usage of reagents within valid dates, analysts must record the _________ and expiry date of the reagents while conducting a particular test.
    - A. Lot number
    - B. Receiving date
    - C. Supplier’s name
    - D. Standardization date
249. For thermal sensitive products which is **TRUE** regarding sterilization?
    - A. Can be achieved by high temperature.
    - B. Can be achieved by low temperature.
    - C. Can be achieved by low temperature & antimicrobial Agent
    - D. None of The Above
250. Freeze dried injectable products have to be reconstituted with _________ to form solution or suspension for administration
    - A. Sterile Water for Injection
    - B. Purified water
    - C. Water for Injection
    - D. Boiling water
251. Deviation noted by the company from expected yield should be considered as
    - A. Financial burden with no quality impact
    - B. A deviation which should be investigated before release
    - C. A deviation which should be investigated apart from the product release procedure
    - D. B and C

252. The acceptable bioburden level prior to the final sterile filtration for products must show a bioburden

A. < 10 CFU/100 ml.
C. > 10 CFU/100 ml.
B. ≥10 CFU/100 ml.
D. ≤10 CFU/100 ml.

253. Which one of the following discrepancies shall **NOT** be dealt with corrective actions?

A. Replace faulty part of a major equipment
B. Product failing specification
C. Confirmed regulatory authority complaints
D. Product recalls after marketing.
E. Products confiscation during routine inspection

254. What is the meaning of integrity testing of sterilizing filters?

A. To test if the filter is intact, normally before and certainly after filtration
B. To test if the filter is intact, normally after filtration
C. To test if the filter is intact, normally before filtration
D. To test if the filter is intact, normally during filtration

255. Range and linearity determination are required for analytical method intended for

A. Assay and Impurity
C. Assay and limit test
B. Limit test and Impurity
D. Assay and dissolution

256. Which area of the manufacturing should be considered for ongoing verification according to the new WHO GMP sterile manufacturing guide?

A. Personnel
B. Raw materials
C. Facility, equipment, and process
D. Process validation

257. Which type of validation involves historical data to demonstrate that a process has consistently produced product that meets predetermined specifications?

A. Prospective validation
C. Retrospective validation
B. Concurrent validation
D. Revalidation

258. In the case of aseptic processing, environmental quality records should be examined in conjunction with the results of the sterility test

A. True
B. False

259. Which one of the following statements is/ are **FALSE** about annual product review?

A. There is no limit for the maximum number of batches to be incorporated

B. Information available in the validation report need not be repeated in PQR

C. Typically, be carried out for each product manufactured in the previous year.

D. PQR may be grouped by product type or dosage forms.

E. Individual effect of a process or manufacturing change should be considered when reviewing the impact of changes in applying change control procedure.

260. The process of sterilization is used for which dosage forms?

A. OSD B. Parenteral drugs C. Ophthalmic drugs D. B & C

261. The action taken to eliminate the already detected causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

A. Remedial

B. Preventive

C. Corrective

D Corrections

262. Quality control is

A. Confined to laboratory functions only.

B. Part of GMP concerned with all the sampling, specifications and testing and the organization, documentation and release procedures to ensure quality.

C. Dependent on the production department for all its staffing and budgets.

D. Not required by small manufacturers.

263. **INCORRECT** about the ICH Q3C(R8) guideline regarding residual solvents

A. Does not apply to potential new API, excipients, or FPP used during the clinical research stages of development,

B. Not applied to existing marketed drug products.

C. Applies to all dosage forms and routes of administration.

D. Testing of the drug product for residual solvents need be considered at the level equal to or below the recommendation of this guideline.

E. Higher levels of residual solvents may be acceptable in short term usage or topical application.

264. Master copies of documents should be signed by

A. The author alone.

B. The technical director.

C. The QC manager.

D. The author plus authorization signatories.

265. Storage and distribution arrangements for the product

A. Are not the responsibility of the manufacturer once it has left his factory.

B. Have no impact on product shelf-life or product quality.

C. Have to be satisfactory as far as possible throughout the supply chain to ensure quality is maintained.

D. Is the responsibility of government.

266. Stability Data for Climatic zone III & IV comes under___________ ICH guideline

A. Q1C B. Q1E C. Q1F D. Q1D

267. Under quality assurance a company should have procedures that

A. May be updated before a GMP inspector announces an inspection.

B. Provide for self-inspection and a quality audit to regularly appraise effectiveness and applicability of the QA system.

C. Are only written and used by senior management.

D. Must only be in the language that the GMP inspectors understand.

268. The purpose of performance qualification is to check

A. Has it been built correctly? C. Has it been designed correctly?

B. Does it produce product correctly? D. Does it work correctly?

269. Under GMP a company should investigate complaints

A. About marketed products and take appropriate action to prevent reoccurrence of justified complaints.

B. Only when we know that government may insist on a recall.

C. Only if the company believes the person making the complaint is truthful and is not just looking for a free replacement.

D. Only if the production department agrees.

270. Cleaning validation acceptance criteria use the formula, C = (dbF)/dn to calculate the maximum carry-over concentration (C) permitted per 100 cm^2 of contact surface. If d, b, F and dn represent: therapeutic dose, batch size, safety factor and largest daily dose of new product to be manufactured, respectively, then calculate C if: d = 100 mg/tablet, b = 100 kg, F = 0.1 and dn = 250 mg/tablet. What type of product is this likely to be, based on the safety factor?

A. 4.0 mg, parenteral C. 40 mg, parenteral

B. 4.4 mg, topical D. 4.4 mg, solid dosage form

271. Sampling of materials such as starting materials, primary packaging materials and products, should be carried out in the same environmental conditions that are required for further processing of the product.

A. True B. False

272. Which validation of tests for assay and for quantitative determination of impurities or purity typically includes to determine the investigation of precision.

A. Repeatability and intermediate precision

B. Reproducibility and intermediate precision

C. Repeatability and reproducibility

D. Repeatability, reproducibility and intermediate precision.

273. A holder of a manufacturing authorization

A. Does not need to have a quality control department.

B. Does not need adequate facilities if he/she has excellent people.

C. Can confine the quality control department to the laboratory only.

D. Must provide adequate resources to ensure that all quality control arrangements can be reliably carried out.

274. The stability study should be performed in the primary and secondary packaging intended for long-term commercial storage and transportation.

A. True B. False

275. In case, the ____________ are opened and used to test for investigation, documentation must be done to indicate reason for opening to keep the track of usage.

A. Finished products C. Raw materials

B. Retention samples D. Packaging samples

276. The purpose of a validation master plan is

A. To list the tests and acceptance criteria for the entire validation programme.

B. To provide an overview of the policy on validation.

C. To record the results of tests carried out during validation.

D. All of the above.

277. The microbiological limit of purified water is

A. NMT 500 CFU per ml C. NLT 100 CFU per ml

B. NMT 10 CFU per 100 ml D. NMT 100 CFU per 10 ml

278. Which statement is **TRUE** about performance characteristics of reproducibility
    - A. The variation of reproducibility is often greater than the repeatability
    - B. Larger precision values, in reproducibility as a result of greater variation
    - C. Once reproducibility is assessed, a measure of intermediate precision is not required.
    - D. Investigation of reproducibility is usually not required for regulatory submission.
    - E. All

279. Who is responsible for conducting GMP trend analysis?
    - A. Quality control department
    - C. Manufacturing department
    - B. Regulatory affairs department
    - D. Quality assurance department

280. By which method endotoxins and pyrogens can be significantly removed from water
    - A. Distillation and double pass RO.
    - C. Deionization only.
    - B. 0.22-micron filters and UV.
    - D. Active carbon and Distillation.

281. The system of quality assurance should ensure that
    - A. Management responsibilities are clearly specified in job descriptions.
    - B. The FFP is correctly processed and checked according to defined procedures.
    - C. Production and control operations are clearly specified in a written form and GMP requirements are adopted.
    - D. The products are designed and developed in a way that considers GMP and other codes of practice.
    - E. All of the above.

282. The risks that GMP are designed to reduce are
    - A. In principle mix-ups and cross contamination.
    - B. Wrong labelling of the finished pack only and cross contamination.
    - C. Expected cross contamination and mix-ups.
    - D. Injury or death due to side effects of the drug.

283. Which statement is **TRUE** for replacement of the HEPA filter
    - A. When a single probe reading is equivalent to 0.01 percent of the upstream challenge
    - B. When nonuniformity of air velocity across an area of the filter is detected
    - C. When airflow patterns are adversely affected by nonuniformity of air velocity.
    - D. When the HEPA filter final pressure drop reading of 450 Pa
    - E. All

284. The following information should be considered as part of inspections preparation
    A. Previous inspection reports
    B. Site Master File
    C. Marketing authorization dossiers
    D. ADR following immunization (AEFI)
    E. All above
285. Water can be considered as
    A. Starting material B. Bulk product. C. Intermediate product. D. All
286. What should be summarized during the review period of a product process and/or its manufacturing process of any given product?
    A. All batches of starting and packaging materials received in a year and their approval status especially those from new sources.
    B. Vendor assurance of new suppliers, including supply chain traceability of active substances
    C. Compilation of the Certificate of analysis results obtained from supplier/manufacturer, if the batch is released based on supplier's CoA.
    D. Details related to any significant deviations observed such as rejection of vendor lots.
    E. All
287. What is the role of management in a pharmaceutical quality system?
    A. To delegate all responsibility for quality to employees
    B. To ensure that adequate resources are available for quality activities
    C. To ignore quality issues until they become critical
    D. None of the above
288. Phase II water system validation is carried out for
    A. 30 days B. 1-year C. 2 weeks D. Around 3 months
289. Filter classes should always be linked to the standard test method because
    A. Referring to actual filter efficiencies is very misleading
    B. Different test methods result in a different value for the different filters.
    C. Referring to actual filter efficiencies is the preferred method
    D. Different test methods result in a different value for the same filter.
    E. A and D

290. Which one is/are causes for cross contamination?
    - A. Poorly designed air handling systems and dust extraction systems
    - B. Poorly operated and maintained air handling systems and dust extraction systems
    - C. Inadequate procedures for personnel and equipment and Insufficiently cleaned equipment
    - D. All of the above
291. Which solid phase entraps more moisture?
    - A. Eutectic B. Crystalline C. Amorphous D. Lyotropic
292. FAT is test conducted at the site of use to verify that the system, equipment or utility, as assembled or partially assembled meets expected specifications.
    - A. True B. False
293. What are the three typical phases that form in the interstitial space of a frozen solution?
    - A. Stable glass, liquid crystal, and eutectic
    - B. Stable glass, metastable glass, and ice
    - C. Ice, metastable glass, and eutectic
    - D. Stable glass, metastable glass, and eutectic
294. Range determination is required for analytical method intended to
    - A. Identification B. Limit test C. Potency D. Dissolution
295. Stability testing is done
    - A. To determine shelf life of product C. To determine packaging components
    - B. To get data at pre-formulation stage D. All of the above
296. The choice of sterilisation method is dependent on
    - A. The procedure of preparation of the components.
    - B. Automated filling and sealing.
    - C. The temperature in the area.
    - D. The properties of the materials and product.
297. The internal diameter of pipes for a dead leg in a water system should be
    - A. NMT 3x of the ID C. NLT 1x of the ID.
    - B. NMT 2x of the ID. D. NLT 3x of the ID
298. In the case of aseptic processing, environmental quality records should be examined in conjunction with the results of the sterility test before release.
    - A. True B. False

299. Which two instruments are typically used to determine the end of primary drying?
   - A. CM gauge and thermocouples
   - B. Sample thief and Karl Fischer
   - C. Karl Fischer and thermocouples
   - D. Pirani gauge and thermocouples

300. Which statement is **TRUE** about sterile manufacturing?
   - A. Air monitoring samples of critical areas should yield no microbiological contaminants.
   - B. When 99.9% level of depyrogenation by dry heat has been successfully validated using endotoxin challenge, a sterilization validation using a biological indicator challenge would not be indicated.
   - C. For grade D supporting rooms, airflow sufficient to achieve at least 20 air changes per hour is typically acceptable.
   - D. Significantly higher air change rates are normally needed for grade C and grade A areas.

301. The minimum concentration of hydrogen peroxide used in VHP sterilization?
   - A. 3%
   - B. 6%
   - C. 35%
   - D. 60%

302. During the primary drying phase what is necessary to calculate amount of heat required?
   - A. Using latent heat of sublimation
   - B. Using enthalpy
   - C. Using latent heat of vaporization
   - D. Using specific heat

303. During freeze drying process at what point does the ice crystal formation takes place?
   - A. When the material is cooled below its triple point
   - B. When the material is cooled below its freezing point
   - C. When the material is cooled below its dew point
   - D. When the material is cooled above its triple point

304. Recharging of Zeolite column is done by
   - A. Steam
   - B. Back flushing
   - C. NaCl
   - D. NaOH

305. The purpose of bracketing and worst-case in cleaning validation results is?
   - A. To demonstrate compliance with regulatory requirements
   - B. To identify areas for improvement in the cleaning process
   - C. To track trends in cleaning validation results over time
   - D. All of the above

306. Which one governs the process in secondary drying in freeze drying?
   - A. Latent heat of sublimation
   - B. Enthalpy
   - C. Latent heat of vaporization
   - D. Adsorption isotherms

307. Accuracy determination is **ONLY** required for analytical method intended for
   A. Assay and quantitative limit test C. Assay and limit test
   B. Limit test and quantitative limit test D. Assay and dissolution
308. What is a triple point of pure water?
   A. -0.01°C B. 0.01°C C. 0.1°C D. -0.1°C
309. One of the following is the objective of PQ
   A. To ensure that the equipment which gives acceptable results without load will produce the same results under load.
   B. To ensure that the system, utility or equipment is appropriate and ready for dispatch.
   C. To verify the acceptability of the system, utility or equipment.
   D. To ensure that the system operates according to the described specifications
310. How long does freeze drying take?
   A. 10 to 40 hours B. 20 to 40 hours C. 30 to 50 hours D. 5 to 20 hours
311. One of the following is **NOT** an activity carried out during PQ?
   A. Checks based on product analysis of the connected production facilities
   B. Tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process and the facilities, systems or equipment
   C. Low medium and high ranges, upper and lower operating ranges, including "worst case" conditions are verified.
   D. Test is performed without load and different operational ranges in empty or as built conditions with supplies and connections.
   E. Test to ensure that the equipment which gives acceptable results without load will produce the same results under load using placebo batches.
312. Quality assurance is a
   A. Covers only the administrative arrangements relating to product quality.
   B. Limited activity relating to the product release procedures only.
   C. Wide-ranging concept covering all matters that influences product quality.
   D. Philosophy that gives general guidance only and is issued by top management.
313. What are factors depending on rate of drying?
   A. Composition of raw material C. Initial moisture content of the product
   B. Temperature, RH D. All.

314. The relationship between product temperature and vapor pressure in freeze drying?

A. Exponential B. Direct C. No relationship D. Inverse

315. The basic elements of validation are

A. Evidence that all aspects of a manufacturing process achieve the expected result.

B. Documented evidence that all aspects of systems, facilities, equipment and manufacturing processes achieve the expected result.

C. Documented evidence that the equipment used in manufacturing works as it is intended

D. A record of how a manufacturing process works.

316. Purpose of specifying limits or frequencies or ranges in Annex 1 sterile manufacturing is?

A. To ensure regulatory compliance

B. To set maximum requirements for contamination control

C. To provide historical regulatory experience

D. To facilitate manufacturing process optimization

317. What is cryodesiccation?

A. Freeze drying B. Pasteurization C. Irradiation D. Dehydration

318. Which one is **NOT** a component of a risk management system in a PQS?

A. Risk assessment C. Risk evaluation

B. Risk avoidance D Risk communication

319. Which analytical figures of merit is **INCORRECT** about typical industrial practice for verification of compendial procedure

A. Specificity, accuracy, and repeatability are required

B. LOD and LOQ, each demonstrate 50% of the specification

C. Linearity, Range and Robustness are not required

D. Verification required for basic qualitative pharmacopoeial methods

320. The results of any analysis can only be meaningful if the ____ is undertaken effectively.

A. Processing C. Testing

B. Sampling D. Reviewing

321. What approach should be used in the design and control of facilities, equipment, systems, and procedures for the manufacture of sterile products?

A. Quality Risk Management (QRM) C. Standard operating procedures (SOPs)

B. Statistical process control (SPC) D. Lean manufacturing principles

322. The term “labeling” refers to printed, written, and graphic material:
   A. On the primary container of the drug product
   B. On secondary containers and wrapping
   C. On printed, written, and graphic material accompanying the drug product
   D. All of the above

323. A significant change in stability study is a failure to meet to which one of the following predefined specification/s.
   A. A 5% potency change from the initial assay value;
   B. Any specified degradation product and pH exceeding its acceptance criterion
   C. Failure to meet acceptance criteria for color, phase separation, caking, hardness
   D. Dissolution exceeding the acceptance criteria for 12 dosage units.
   E. All

324. An analytical method usually compares the instrumental response of the unknown analyte with that of a standard sample. Which of the following is the most significant instrument performance characteristic for this measurement?
   A. Accuracy
   C. Trueness
   B. Intermediate Repeatability
   D. Reproducibility;
   E. Repeatability

325. Deviations are not categorized as changes, not even when they are accepted as changes after errors have been eliminated.
   A. True
   B. False

326. As inspector where exactly do we expect the documentation to be clearly stated the commitment of a company to maintain continued validation status
   A. Quality manual or validation master plan.
   B. Quality objective or validation master plan.
   C. Quality manual or validation protocol plan.
   D. Quality planning or validation summary.
   E. A and C

327. According to EU and WHO sterile manufacturing guideline; at the most vulnerable points where sterilized containers and closures are exposed and filling and sealing operations occur, air should be supplied with > 3520 particles of $\geq 0.5\ \mu m$ for Grade A and with 1CFU/10ft^3
   A. True
   B. False

328. Qualification normally start with the preparation of user requirement specifications (URS) followed by DQ, IQ, OQ and PQ.

A. True B. False

329. Which one is **INCORRECT** about retrospective validation?

A. It is often performed during the development stage of pharmaceutical product

B. It involves analysis of batches manufactured over a period of 12 months without significant change on the manufacturing process

C. For existing (legacy) processes it must be replaced with prospective validation studies in order to meet current standards and expectations

D. Generally, data from consecutive batches of 10 per year to 25 per three years should be examined to assess process consistency

E. All of the above

330. Generally, the cGMP requirement for document retention time for QC test records are shorter compared to GLP documentation requirement as per WHO.

A. True B. False

331. **TRUE** statement about quality assurance is?

A. It is the measurement of degree to which a product satisfies the need of a customer

B. Any systematic process used to ensure quality of a product in the process

C. It is a corrective tool

D. Process of identifying non-conformance in a product

E. It is related to the validation of system

332. Which one is appropriate to consider the following factors in evaluating the adequacy of measures to be taken to preclude contamination of materials during processing?

A. The type of manufacturing system as open or closed and the form of the material under processing such as wet or dry processing.

B. Stage of processing and use of the equipment in both or either of a multipurpose or dedicated manufacturing area

C. Degree of exposure of the material to adverse environmental conditions and the relative ease and thoroughness of clean-up.

D. Aseptic versus non-sterile manufacturing operations.

E. All sounds suitable factors to consider.

333. The differential pressure between zones of different classes of controlled environments should be 10–15 Pa with doors closed being measured across the doors of each air lock

A. True B. False

334. The PQR conclusion must **NOT** be delayed by more than the __________ of next year.

A. First month C. First quarter

B. Second quarter D. Two weeks

335. Master formula

A. Can be hand copied to provide operating instructions

B. Must be signed and dated by competent persons experienced in production and QC

C. Can be amended until the process has settled down. Process operator can make the amendment

D. Only gives information on the quantity of the starting materials and the yield

E. A and B

336. Specificity determination may **NOT** require for analytical method intended to

A. Dissolution test C. Potency

B. Identification test D. Limit test

337. For sterilization to occur, steam must

A. Make direct contact with all surface C. Be superheated

B. Be flushed into each package D. Trap air inside the package

338. Decision points are **NOT** shown in ICH Q9 QRM diagram.

A. To return/reassess to the previous step

B. To seek further data/ information or adjust the risk models

C. To terminate QRM process based upon supporting information for decision.

D. All are correct statements

339. Which one of the following is **INCORRECT**?

A. Not all corrective actions will have associated preventive actions.

B. Conformity to the requirements shall be verified when nonconforming outputs are corrected.

C. The preventive action should prevent the (first-time) occurrence of the potential issue

D. A remedial action are taken to alleviate the immediate symptoms

E. CAPA is reviewed in premarket approval applications 510(k)

340. In general, a matrixing design is applicable
   A. If the supporting data indicate predictable product stability.
   B. When the supporting data exhibit only small variability or moderate variability, a matrixing design should be statistically justified.
   C. If the supportive data show large variability, a matrixing design should not be applied.
   D. The stability of each subset of samples tested represents the stability of all samples at a given time point
   E. All
341. Its goal is control of the manufacturing process and enhanced process understanding, guided by risk management.
   A. Process design C. PAT
   B. Process performance qualification D. Continued process verification
342. What is cleaning validation?
   A. The process of validating the cleanliness of equipment and surfaces used in manufacturing
   B. The process of validating the efficacy of cleaning agents used in manufacturing
   C. The process of validating the effectiveness of a cleaning procedure in removing residues
   D. The process of validating the safety of cleaning agents used in manufacturing
343. Sterility assurance level
   A. It means that out of 1 million units NMT 1 unit may show growth
   B. It is one of the QC tests specified for release of a batch of sterile product.
   C. It may assist in identifying a non- sterile batch of product.
   D. Only for terminally sterilized products
344. What is the main advantage of annealing in lyophilization?
   A. To achieve large ice crystals C. To achieve small ice crystals
   B. To achieve microscopic ice crystals C. To achieve both ice crystals types
345. The results of any analysis can only be meaningful if the ____ is undertaken effectively.
   A. Processing B. Testing C. Sampling D. Reviewing
346. As per procedure, each ____________, a collective report based on quantitative and qualitative results of all test will be published for each product.
   A. Subsequent year C. Month
   B. Quarter D. Two years

347. What type of information is typically included in a Type I DMF?
   - A. Manufacturing process and controls for the drug substance
   - B. Analytical methods and specifications for the drug substance
   - C. Stability data and storage conditions for the drug substance
   - D. All of the above

348. A self-inspection should be carried out
   - A. Only before a government GMP inspection is due as an additional check.
   - B. During every shut-down period.
   - C. Once a year or as directed by the GMP inspectors.
   - D. According to an appropriate written schedule.

349. Quality risk management is defined as
   - A. It is a systematic process for the assessment, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.
   - B. It is a systematic process for the assessment, control, and review of risks to the quality of the drug (medicinal) product across the product lifecycle.
   - C. It is a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.
   - D. It is a systematic process for the assessment, control and communication of risks to the quality of the drug (medicinal) product across the product lifecycle.

350. Finished product QC assessment should embrace all **EXCEPT**
   - A. Includes the results of in-process testing.
   - B. Includes assessment of manufacturing, packaging and quality control documentation.
   - C. Includes assessment of compliance of the product with the specifications.
   - D. Excludes an examination of the finished pack if everything else is satisfactorily.

351. Type T thermocouples are most applicable in steam sterilizer qualification work.
   - A. True B. False

352. What is the purpose of a validation study in cGMP manufacturing?
   - A. To ensure that a process consistently produces a product that meets its specifications
   - B. To test a product on human subjects before it is released to the market
   - C. To determine the shelf life of a product
   - D. To assess the safety of a product

353. Defective equipment
    A. Should be covered up until any inspector has passed by.
    B. May be used if the supervisor decides the defect is not too serious.
    C. Should, if possible, be removed from the area or clearly labelled as defective.
    D. May be used if production is going to be delayed providing it is repaired before the next batch.
354. Non-parenteral type of glass consists of which of the following type?
    A. I B. III C. II D. IV
355. Integrity tests for a filter are performed
    A. To detect damaged membrane
    B. To detect system leak
    C. To detect ineffective sealing of filter
    D. All
356. What should be summarized during the review period of a product process and/or its manufacturing process of any given product?
    A. Review/report of the impact of the changes on the quality of the product and to ongoing stability, especially stability groupings
    B. The number of products registered with local and overseas authorities that were covered in the review document including those submitted but not approved/refused
    C. Batches returned, complaints received in a year, batches recalled, together with their reasons, investigation reports and CAPA taken
    D. Review of written contract covering the technical requirements on periodic maintenance of production and laboratory equipment between the manufacturer and supplier and between the contract giver and contract acceptor.
    E. All
357. Why must the product be kept below the critical temperature during freeze-drying?
    A. It will collapse
    B. It will melt
    C. It will dissolve
    D. It will break the vial
358. **TRUE** about both biological indicator and chemical indicator
    A. Both indicate whether the sterilization process has passed/failed
    B. Not necessarily prove that the process has been successful.
    C. they do not give a reliable indication that the batch is in fact sterile
    D. BIs are much less reliable than physical monitoring methods F_0

359. All of the following activities and requirements are unique to the buffer area **EXCEPT**?

A. ISO Class 7 air quality

B. Contains only necessary equipment, supplies, furniture

C. Items brought in should be nonpermeable, non-shredding, and resistant to disinfectants.

D. May have a laminar airflow hood ISO class 5 within this area.

E. May perform ante-room activities if a positive-pressure differential exists.

360. Why is cleaning validation important?

A. To ensure that residues from previous manufacturing runs do not contaminate subsequent batches

B. To ensure that cleaning agents are safe for use in manufacturing

C. To reduce manufacturing costs by reducing the frequency of cleaning

D. To increase profits for manufacturers

361. Printed packaging components

A. Do not need any special precautions because they are so cheap.

B. If obsolete, can be given to the waste disposal contractor in complete packs with no need to destroy them.

C. Do not need to be handled like other starting materials because they are so cheap and therefore less important.

D. Should be issued for use only by designated personnel using an approved and documented procedure.

362. Recovery rate testing determines the period of time needed for a cleanroom to reduce a contamination event, or “clean up”, by what factor of log reduction?

A. 1 or 2 log B. 3 log C. 2 or 3 log D. 4 log

363. Premises used for the manufacture of drug products

A. Should be constructed as economically as possible.

B. Do not have to control entry of pests if all processes are fully enclosed.

C. Only need maintenance when something breaks down.

D. Should be designed and constructed to facilitate good sanitation.

364. Which one can occur if packages are moist at the end of the steam cycle?

A. Mold can form on the package C. It will be too hot to handle

B. Bacteria can wick into the package D. None

365. Incoming materials should be
   - A. Released for use immediately if needed urgently for a life-saving product.
   - B. Quarantined immediately after receipt until released for use or distribution.
   - C. Used if they were delivered inadvertently to your factory.
   - D. Purchased according to a specification developed by the finance department.
   - E. A and B
366. Shelf life, expiration date, and storage conditions assigned for a drug product should be supported by long term stability storage and testing of an adequate number of batches.
   - A. True B. False
367. For a given analytical method's intermediate precision, the instrument may reflect discrepancies as a result of which factor/s listed below?
   - A. The inconsistent working practice of different analysis's
   - B. The application of different instruments
   - C. Standards and reagents purchased from different suppliers
   - D. Columns used from different batches
   - E. Any combination of A to D
   - F. All could be the factors associated with intermediate precision.
368. Freeze dried injectable products have to be reconstituted with _________ to form solution or suspension for administration
   - A. Sterile Water for Injection C. Water for Injection
   - B. Purified water D. Boiling water
369. Which one is **NOT** the objective of the stability study?
   - A. To ensure that the material under investigation will remain within specification during its assigned retest or expiry period,
   - B. To establish the shelf life of an API or the retest period of FPP.
   - C. To identify any underlying trends or any changes that could be considered to be significant.
   - D. To fulfill the regulatory requirement for dossier submission.
   - E. To confirm the retest period of an API or the shelf life of FPP.
370. As per ICH guidelines Chloroform is classified as
   - A. Class I solvent B. Class III C. Class II solvent D. Class IV

371. Balances and other measuring equipment should be checked for effectiveness
    - A. On a scheduled basis.
    - B. Before an inspector comes.
    - C. Before the manager comes into the department.
    - D. After the balance maintenance engineer has performed maintenance.
372. BCS classification for Class III drugs is
    - A. High solubility high permeability
    - C. Low solubility high permeability
    - B. High solubility low permeability
    - D. Low solubility Low permeability
373. Starting materials
    - A. Do not need to be tested on receipt if the owner of the vendor is known personally to the manager of the buying facility
    - B. If coming from one supplier does not need to be tested
    - C. If hazardous does not necessarily need to be tested if there is a batch certificate of analysis from the vendor
    - D. Does not have to be listed on the batch processing instructions if supplied in bulk
374. One of the organisms given below is used as biological indicator for VHP sterilization. Choose the **CORRECT** one:
    - A. Bacillus stearothermophilus
    - C. Bacillus subtilis
    - B. Bacillus pumilus
    - D. Geobacilus stearothermophilus
375. The quality control department
    - A. Does not need to ensure that stability is tested if there is a development department
    - B. Does not need a laboratory if the client is willing to do all the testing
    - C. Is responsible for the investigation of all complaints related to quality of active ingredients
    - D. Does not approve reprocessing instructions that is the responsibility of production and development
376. The selection, qualification, approval and maintenance of suppliers of packaging materials and starting materials should be document a part from PQS.
    - A. True
    - B. False
377. Review of master documents should take place
    - A. Every 6 months.
    - C. Place every 12 months.
    - B. Is not necessary once approved.
    - D. According to a pre-defined schedule.

378. Quality by design is a concept introduced by the ICH as ___ guideline

A. ICH Q5 B. ICH Q6 C. ICH Q7 D. ICH Q8

379. Pilot scale-up studies are done before taking full scale validation batches

A. To optimize the manufacturing process conditions at plant level

B. To confirm the suitability of equipment used for manufacturing

C. To confirm the consistency of quality of product manufactured at plant level

D. To optimize the manufacturing process conditions, confirm suitability of equipment, consistency of quality of products manufactured at plant level

380. The guideline ICH Q1A (R2) refers to

A. Stability study of new molecular entities and associated drug products.

B. Generation of photostability information

C. Analytical validation

D. Impurities

381. ___ is the time necessary for the concentration of the reactant to decrease to 90% of its original concentration?

A. Product life C. Half-life

B. Shelf life D. None of the above

382. In most respects the Bioburden method is similar to the Bioburden/BI indicator method for the sterilization cycle development. **EXCEPT** the bioburden method

A. Biological indicators are required for sterilization cycle development for bioburden method to be employed

B. It must be cultured to produce a suitable challenge MOs and demands the isolation and characterization of the most-resistant bioburden microorganism

C. The worst-case isolate is used instead of biological indicators to evaluate the sterilization process.

D. The bioburden of each process cycle must be closely controlled and monitored with respect to population and resistance.

E. All are correct except “A”

383. Powdered glass test challenges the leaching potential of:

A. Exterior structure of glass C. Plastic containers

B. Interior structure of glass D. Intact surface of glass

384. According to WHO, at what statistically defined limits should be water for pharmaceutical use to assess whether a system is statistically able to meet a set of specifications.

A. 3 sigma level, Ppk/Cpk =1 C. 3 sigma level, Cpk =1

B. 2 sigma level, Cpk =1 D. 2 sigma level, Ppk/Cpk =1

385. The frequency of cleaning programme:

A. Depends on the function and activities undertaken in the area

B. Performed according to number of times specified by WHO

C. Performed according to the availability of cleaning agents and number of cleaners

D. Both A and B

386. Which of the following documents provides information about the performance of a task

A. Standard Operating Procedure

B. Quality Policy

C. Product Master File/Formulae

D. Batch Manufacturing Record

387. Which of the following statement best represent a risk-based approach to documentation review.

A. Request and review all documents before a GMP inspection

B. Review all documents at inspection site

C. Request and deep dive the review of relevant documents related to type and scope of inspection arising from findings during a GMP audit

D. Request and review uncontrolled copies of quality system document since there may not be enough time to do so during the audit

388. Using a risk-based approach inspection, when does a follow-up inspection would be expected for a manufacturing site with identified deficiencies

A. When a site has had a critical or ≥ 6 minor deficiencies are identified.

B. When a site has had a critical or ≥ 2 minor deficiencies are identified.

C. When a site has had a major or ≥ 5 minor deficiencies are identified.

D. When a site has had a major or ≥ 2 minor deficiencies are identified.

389. Since DQ is carried out before purchasing the equipment, Validation Protocols should be developed only for IQ, OQ, PQ during execution.

A. True B. False

390. **TRUE** features about closed isolators
    A. Maintain Grade B conditions and ensure first air
    B. Air does not need to be unidirectional, but the risk of turbulent air must be understood
    C. Located in a Grade C cleanroom (minimum)
    D. Airflow visualization must focus on open area interfaces
391. Cryoprotectants or lyoprotectant used in freeze dried parenteral products
    A. Mannitol B. Starch C. Magnesium stearate D. PVP
392. A manufacturer of pharmaceutical product shall deal with nonconforming outputs with which one or more of the following ways:
    A. Correction and informing the regulatory agency oversighting the manufacturing
    B. Segregation, containment, return or suspension of provision of products and services
    C. Obtaining authorization for acceptance under concession.
    D. All
393. The highest feasible temperature for batch sterilization is
    A. 124°C B. 120°C C. 121°C D. None of these
394. Which of the following is a GMP requirement for documentation?
    A. To put the pharmacopoeia specifications for raw materials into a company authorized document.
    B. To tell people what to do and when.
    C. To make sure the process operators have something to do while waiting for a manufacturing step to finish.
    D. To provide an audit trail in the case of a justified customer complaint.
395. Its goal is, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing.
    A. Process design C. PAT
    B. Process performance qualification D. Continued process verification
396. Materials dispensed for a batch
    A. Can be dispensed by one person with no checks if that person is a pharmacist.
    B. Should be kept together and clearly labeled as such.
    C. Can be sent item by item to the production department, as it wants them.
    D. Do not need to be labeled if they are going to an area that only ever makes one product.

397. Which of the following is an International regulatory authority for drug regulation?

A. TGA B. US-FDA C. WHO D. EMA E. All

398. Which approaches is **NOT** in ICH Q2 for the determination of both LOD and LOQ

A. Visual evaluation
B. Standard deviation of the response based on blank
C. Signal to noise ratio
D. Standard deviation of the slope based on calibration curve
E. None of the above

399. The sequential steps involved in freeze drying of parenterals are

A. Freezing, Vacuum Drying, Sublimation
B. Vacuum Drying, Freezing, Sublimation
C. Freezing, Sublimation, Vacuum Drying
D. Sublimation, Vacuum Drying, Freezing

400. In Overkill design approach

A. A worst-case bioburden assumption is used to determine the delivered lethality needed to achieve a Probability of a non-sterile unit of 10^{-6} on or in the items being sterilized.
B. The approach negates the need to determine D-value of microbe and the need test sample for bioload before running the cycle.
C. The accepted criterion for sterility is reported as the probability of survival of no greater than or $\leq 10^{-6}$ CFU and all BI's are killed
D. The approach employs many more microbes and exceeding time than would find on items typically sterilized using autoclaved sterilization method.
E. All are correct answers

401. Prospective validation done when there is a __________in the manufacturing process

A. Consistency B. Change C. Uniformity D. Similarity

402. Grade A aseptic area used for manufacturing of ophthalmic solutions prepared by membrane filtration comprises of:

A. Not more than 100 particles per cubic meter of size 0.5 microns
B. Not more than 100 particles per cubic foot of size 0.5 microns
C. Not more than 1000 particles per cubic foot of size 0.5 microns
D. Not more than 1000 particles per cubic meter of size 0.5 microns

403. FDA Type I DMF deals with

A. Packaging B. Manufacturing Site C. Drug substance D. Excipients

404. Class 1,00,000 is _____ number of particles of size ____or larger per cubic foot of air

A. 100 and 5 µm C. 1,00,000 and 0.5 µm

B. 1000 and 0.05 µm D. 10,000 and 0.005 µm

405. What is the purpose of rinse sampling in cleaning validation?

A. To collect samples from equipment and surfaces after they have been rinsed with water

B. To collect samples from equipment and surfaces before they are cleaned

C. To collect samples from cleaning agents before they are used in manufacturing

D. To collect samples from finished products to ensure they are free of residues

406. Which one of the following discrepancies shall **NOT** be dealt with preventive actions?

A. Trend analysis for stability monitoring data

B. Production yield variations or discrepancy (Reconciliation)

C. Product returns for further reprocessing

D. Revalidation data

407. Where capping is a manual process, it should be either performed under

A. Grade A conditions in designed isolator C. Grade A with a grade B background.

B. Grade A with a grade C background. D. In either of A or B conditions

408. What is the minimum air change rate required in a pharmaceutical cleanroom?

A. 1 air change per hour C. 10 air changes per hour

B. 100 air changes per hour D. There is no minimum requirement

409. Sterilization is?

A. The process of removing visible dirt and debris from surfaces

B. The process of killing all MOs on surfaces or in a product

C. The process of reducing the number of MOs on surfaces or in a product

D. The process of disinfecting surfaces or products

410. Which one is **FALSE** regarding the sterilization validation process?

A. D value of 2.0 is more resistant than a D value of 1min.

B. Fo accumulate as the sterilisation cycle progresses

C. Overkill approach negates the need to test sample for bioload before running the cycle

D. Biological indicators assist in the OQ of the sterilization equipment

411. Which one is **NOT** ICH Q10 in product life cycle goal is/are

A. Pharmaceutical Development
C. Technology transfer
B. Commercial Manufacturing
D. Product Realization

412. What are acceptance criteria in cleaning validation term?

A. The criteria used to determine whether a cleaning procedure has been successful in removing residues
B. The criteria used to determine whether a cleaning agent is safe for use in manufacturing
C. The criteria used to determine the cost-effectiveness of a cleaning procedure
D. The criteria used to determine the profitability of a manufacturing process

413. Filters of HVAC in pharmaceutical industries are

A. HEPA Filters B. Bag filters C. Prefilters D. All

414. Incoming materials should be physically and administratively quarantined immediately after receipt, until they have been released for use.

A. True B. False

415. **TRUE** regarding sterility test

A. It is limited in its ability to detect contamination as it utilizes only a small number of samples in relation to the overall batch size and only provides an opportunity to detect major failures in the sterility assurance system.
B. Testing to a level of statistical significance would require a small sample size and for such tests, it would be practically and economically unsustainable.
C. The microbial challenge by virtue of their fastidious nature, or physiological prerogative, will not grow on growth medium or only stimulate growth of some
D. A sterility release system based upon batch records review of a validated process in lieu of release procedures based on end-product sterility testing.
E. All are correct answers

416. What is a cleaning validation master plan?

A. A document that outlines the overall strategy for cleaning validation at a manufacturing facility
B. A record of all cleaning procedures performed at a manufacturing facility
C. A record of all residues found during cleaning validation testing
D. A document that outlines the requirements for cleaning agents used in manufacturing

417. Which element is **NOT** considered within a CCS Annex 1 for sterile product?
    A. Product containers and closures
    B. Personnel behavior
    C. Process risk management
    D. Preventative maintenance

418. Which one is **NOT** a type of pharmaceutical cleanroom classification?
    A. ISO 4
    B. ISO 6
    C. ISO 5
    D. ISO 8

419. If the result of the initial laboratory investigation is inconclusive, ____________.
    A. Batch should be immediately discarded
    B. A full-scale laboratory investigation is required
    C. Analyst should be re-trained
    D. Production operator should be re-trained

420. The Sterility test of liquid involves:
    A. Colorimetric Assay
    B. Culturing in the FTG medium
    C. Guinea Pigs Assay
    D. HPLC assay

421. Reviewing instruments calibration and maintenance records is a step of investigation that is conducted during the ____________.
    A. Expanded investigation
    B. Maintenance department's investigation
    C. Laboratory investigation
    D. Analysts personal investigation

422. What is validation in sterilization terms?
    A. The process of verifying that a cleaning agent is safe for use in manufacturing
    B. The process of verifying that a sterilization cycle has been effective in killing all microorganisms
    C. The process of verifying that a product is free from visible dirt and debris
    D. The process of verifying that a manufacturing process is profitable

423. What are process challenge device (PCD)?
    A. Device to measures the temperature and pressure inside a sterilization chamber
    B. A type of cleaning agent used to remove residues
    C. A type of quality control test used to detect residues
    D. A method of documentation required by sterilization regulations

424. The goal is to provide high degree of assurance that the process remains in a state of control during the course of commercial manufacture.
    A. Process design
    B. PAT
    C. PPQ
    D. CPV

425. Which one is **FALSE** regarding parametric release
   - A. Only for terminally sterilized products using moist heat, dry heat and irradiation method of sterilization
   - B. Product will be released with the need to perform a sterility test.
   - C. Development and validation of cycles are based on bioburden, or overkill or bioburden and BIs approach
   - D. For moist heat sterilized products, Bioburden test of the products should be performed after the filling and sealing processes but before the sterilization process.
426. Overkill approach is mainly employed
   - A. When the quality and function of the product to be sterilized remains unaffected by the sterilization conditions.
   - B. Generally, extremely high F_0 values are used for overkilled approach
   - C. Because the load is heat stable, thermal degradation is of no concern and only the minimum F_0 in the coldest load is considered.
   - D. F_0 that will provide at least a 12-log reduction of microorganisms with a $D_{121°C}$ in one minute to arrive at $F_0 \geq 12$ as a minimum overkill cycle.
   - E. All are correct answers
427. Operational qualification of equipment
   - A. After installation and repair
   - B. After repair
   - C. During installation
   - D. Before installation
428. The process of acquiring and evaluating data to establishes the biological safety of each or a given impurity profile at the level(s) specified
   - A. Impurity Qualification
   - B. Impurity Profile
   - C. Qualification Threshold
   - D. Reporting threshold
429. Process analytical technology applications and multivariate statistical process control can be used at which stage of the process validation for assessment of CQA and PP trends.
   - A. Process design
   - B. Process performance qualification
   - C. Pilot scale up manufacturing
   - D. Continued process verification
430. The F_0 of a process does **NOT** run at 121^{0}C, rather it is the time in minutes required to provide a lethality equivalent to that provided at 121^{0}C for a stated time.
   - A. True
   - B. False

431. The objective of heat-penetration studies during validation of sterilization cycle is/are
    - A. To verify that the sterilizing temperature has been reached in each minimum and maximum load subjected to moist heat sterilization.
    - B. To ensure that the coolest unit within a pre-defined loading pattern is consistently exposed to sufficient minimum "F_0" heat lethality
    - C. To determine slow-to-heat items within the minimum and maximum loading pattern are subjected to moist heat sterilization.
    - D. All
432. The most preferable time for third-party testing is while a product is in the ______ stage.
    - A. Design B. Manufacturing C. Packaging stage D. Development
433. Which one is **TRUE** about residue in pharmaceuticals?
    - A. It is only necessary to test for residual solvents that are used or produced in the manufacture or purification of drug substances, excipients, or drug product.
    - B. As per ICH Q3C(R8) guideline permitted daily exposure is a pharmaceutically acceptable intake of residual solvents.
    - C. All drug substances, excipients, and products are subject to relevant control of residual solvents, even when no test is specified in the individual monograph.
    - D. Acceptable daily intake is used by the WHO to describe exposure limits of toxic chemicals.
    - E. All
434. Which statement hold **TRUE** about glove integrity monitoring.
    - A. A pressure decay and visual inspection associated with each use and following any manipulation that may affect the integrity of the system.
    - B. A vacuum decay and pressure decay following any manipulation that may affect the integrity of the system.
    - C. Only visual inspection associated with each use following any manipulation that may affect the integrity of the system.
    - D. All are true statements
435. Which one is **NOT** a factor that affects cleanroom performance?
    - A. Room temperature C. Room pressure
    - B. Room lighting D. Room humidity

436. For the validation of sterilization cycle heat distribution runs should be performed using
    A. An empty chamber during equipment operational qualification.
    B. The maximum and minimum cycle times, load configurations and temperatures
    C. Multiple temperature sensing devices should be used in each test run throughout the chamber but not inside the units of the load
    D. Different container sizes to be processed using the sterilization parameters specified for the normal production process.
    E. All
437. For aseptically filled products, the probability of sterility or non-sterility depends on
    A. The product environmental controls from clean air devices and cleanrooms
    B. The product filtration, and sterilization of the components to be used for the process
    C. Prior qualification of personnel and gowning qualification requirements
    D. All
438. The technology transfer of production and control procedures of pharmaceutical products from one production site or laboratory to another may only take place before obtaining marketing authorization from the respective regulator authority.
    A. True B. False
439. The function of temperature sensing devices for validation of sterilization cycle is/are
    A. For simultaneous data generation temperature distribution in pre-established time intervals
    B. For the determination of the slowest and fastest heating zones in the chamber.
    C. To determine the effect of any defined loading pattern within the chamber.
    D. All
440. The need for periodic re-validation of non-sterile processes is considered to be a lower priority than for sterile processes.
    A. True B. False
441. What is the purpose of process design in process validation?
    A. To establish the parameters and criteria for the manufacturing process.
    B. To optimize the manufacturing process for maximum efficiency.
    C. To monitor and control the manufacturing process in real-time.
    D. None of the above.

442. A review of the information available about the material under test must be conducted as part of the ____________.

A. Initial investigation
B. Laboratory investigation
C. Expanded investigation
D. Analyst's training

443. When to perform prospective validation?

A. For developing new products.
B. When there is a change in process with a major effect on the product quality.
C. Before starting the routine batches of production.
D. At the stage of product development.

444. The purpose of the overkill method of sterilization approach is

A. To ensure complete sterilization of all microorganisms in a sterilization cycle that exceeds the minimum requirements for autoclave sterilization at 121°C for 15 minutes
B. To assure a significant level of sterility assurance, regardless of the number (BI) and the heat resistance of the organisms in the load (BB).
C. A and B
D. Only A is the correct answer

445. The general SOP for IQ, OQ, and PQ must also describe in detail the requirement of ____________ prior to commencing the qualification process.

A. Master plan
B. GMP guidelines
C. Approved protocol
D. Permission of QA

446. Which one is **FALSE** regarding the compressed gas used for aseptic processing

A. A water and oil content must be specified
B. Gases filters should be subjected to integrity testing per batch bases
C. Transfer piping must be sterile
D. Gases must not be subject to microbial monitoring at point of use on a regular basis

447. Which cleanroom grade is **TRUE** for open product zones of non-sterile dosage form manufacturing facilities.

A. Oral Solid Dosage manufacturing area "at rest" condition Grade D
B. Liquid manufacturing area "in operation" condition, is Grade C
C. Liquid manufacturing area "at rest" condition, is Grade D
D. A and B

448. Which one is **FALSE** regarding CQA of water for pharmaceutical use?
    - A. TOC system suitability is performed with Sucrose and 1,4 Benzoquinone
    - B. Conductivity levels for PW and WFI is the same for both USP and Ph. Eur methods
    - C. TOC levels for PW and WFI the same for both USP and Ph. Eur methods
    - D. Bioburden levels for PW and WFI is the different for both USP and Ph. Eur methods
    - E. All the CQA for HPW and WFI are the same for both USP and Ph. Eur methods
449. Maximum allowable particle size in a cleanroom as per WHO and EU guidelines is

    A. 0.1 µm B. 5 µm C. 0.5 µm D. 1 µm
450. Demonstrating effective product and process understanding aligned with QRM, provides the opportunity in PQS **EXCEPT**
    - A. Facilitate science based pharmaceutical quality assessment and enhance the use of risk-based approaches for regulatory inspections
    - B. Augment science and risk based post-approval change processes to maximize benefits from innovation and continual improvement
    - C. Enable innovative approaches to process validation
    - D. Diminishes the real-time release mechanisms.
451. What are the key stages of process validation?
    - A. Process design, process qualification, and continued process verification.
    - B. Process development, process optimization, and process control.
    - C. Process monitoring, process analysis, and process improvement.
    - D. All are answers
452. What are the acceptance criteria for cleaning validation?

    A. No detectable residue C. Residue below the acceptable limit

    B. Residue within the specified range D. Residue above the acceptable limit
453. Batch documentations
    - A. Are only needed in multipurpose plant
    - B. Are not required if the manufacturing process is automated
    - C. Does not need to mention any contract production
    - D. Should be completed during the production of each batch
454. The individual qualification steps alone do not constitute process validation.

    A. True B. False

455. Which one is **TRUE** about blow fill seal equipment installed for terminally sterilized production facility

   A. Grade D background with non-viable in operation and both at rest and in operation for viable limits

   B. It should be installed in at least a Grade D background

   C. Fitted with an effective Grade A air shower provided that Grade A or B clothing.

   D. Grade D background with viable in operation and both at rest and in operation for non-viable limits

456. In depyrogenation sterilization cycles, which type of spore with a challenge of 10^6 concentration is commonly used.

   A. B. subtilis B. B. pumilus C. B. atrophaeus D. Geobacillus

457. Risk reduction is defined as

   A. It includes actions taken to mitigate the severity, increase detectability, and reduce probability of harm.

   B. Any implementation of risk reduction measures should follow the established CAPA and change control

   C. The implementation of risk reduction measures can introduce new risks into the system or increase the significance of other existing risks.

   D. All

458. Which factor alone does **NOT** give assurance of sterility in sterile product manufacturing?

   A. Raw material testing C. Monitoring systems

   B. Facility design D. Process validation

459. The decisions and actions of outcomes of management review should address and related to

   A. Improvements to the quality system, manufacturing processes and products

   B. Realignment of resources needed

   C. Planned actions should be implemented using CAPA and change control procedures.

   D. The opportunities for improvement and any need for change in the quality system

   E. All

460. A QC lab is using single login & password for HPLC to control the cost of licenses & utilizes a logbook to record run data & analyst details

   A. Attributable B. Legible C. Contemporaneous D. Accurate

461. In pharmaceutical manufacturing, how does senior management could provide support at all levels of the quality system to its effectiveness?
    A. Actively participating in system design, implementation, and monitoring, including system review
    B. Advocating continual improvement of operations of the quality system
    C. Committing necessary resources for the process needed and ensure their availability
    D. Commitment to quality to all levels through policies, objectives, and plans
462. What is the purpose of risk evaluation is
    A. To determine the likelihood of a risk occurring
    B. To determine the severity of the consequences if a risk occurs
    C. To determine the overall risk level and prioritize risk control measures
    D. All
463. What should be annually reviewed during the review period of a product process and/or its manufacturing process of any and every product that have been produced?
    A. Compilation(s) and analysis of in-process test results obtained from the total number of batches manufactured in that particular year and analysis of FPP test results
    B. The number of failed batches/products and the reasons for failure (assignable or non-assignable causes) and all deviations or non-conformance, together with causes of the non-conformance, sorted based on data trending
    C. Review maintenance and calibration records and also the review equipment and process validation schedules for completion
    D. Changes, if any, made to the process and to the analytical methods
    E. All
464. What is a BIs in sterilization terms?
    A. A device that measures the temperature and pressure inside a sterilization chamber
    B. A type of quality control test used to detect residues
    C. A device that contains a known number of microorganisms used to verify the effectiveness of a sterilization cycle
    D. A method of documentation required by sterilization regulations
465. The ISO 9001:2015 standards are based on_______ quality management principles
    A. Five B. Three C. Seven D. Nine

466. All are technical measure approach of prevention contamination in production area. **EXCEPT**
    A. Dedicated manufacturing facility (premises and equipment)
    B. Self-contained production areas having separate processing equipment and
    C. Design of cleaning processes for premises and equipment such that the cleaning processes in themselves do not present a cross-contamination risk
    D. Design lay-out of manufacturing process, premises and equipment to minimize risk
    E. Clean in place automatic systems of validated effectiveness
467. What is the purpose of process validation in a pharmaceutical quality system?
    A. To ensure a process consistently produces a product with predetermined specifications
    B. To comply with regulatory requirements
    C. To reduce manufacturing costs
    D. To maximize profits for the company
468. For method validation which one is **INCORRECT** acceptance criteria for LOD and LOQ
    A. Both LOD and LOQ are required for assay/dissolution methods.
    B. LOD: below the reporting threshold
    C. Signal-to-noise ratio for LOD should be about 3:1.
    D. LOQ: at or below the specified limit
    E. Signal-to-noise ratio for LOQ should be about 10:1.
469. According to EMA guideline; the traditional process validation is normally performed
    A. When the pharmaceutical development is concluded.
    B. After scale-up to production scale
    C. When the pharmaceutical process development is concluded
    D. Prior to marketing of the finished product.
    E. All
470. What is the purpose of a quality manual in a pharmaceutical quality system?
    A. To describe the company's quality management system and its policies, procedures, and processes for ensuring product quality
    B. To comply with regulatory requirements
    C. To reduce manufacturing costs
    D. To maximize profits for the company

471. How often should HEPA filters be tested for leaks?
   A. Every month B. Every 3 months C. Every 6 months D. Every year
472. What is a load configuration in sterilization terms?
   A. The way products are arranged inside a sterilization chamber
   B. The amount of cleaning agent used in a cleaning procedure
   C. The way products are arranged on a manufacturing line
   D. The amount of time a product is exposed to heat during manufacturing
473. What is a process challenge device (PDC) in sterilization terms?
   A. A type of cleaning agent used to remove residues
   B. A device used to simulate the most difficult-to-sterilize part of a product or load
   C. A method of documentation required by sterilization regulations
   D. A device that measures the temperature and pressure inside a sterilization chamber
474. What is a sterility assurance level in sterilization terms?
   A. The probability of a product contaminated with microorganisms after sterilization
   B. The probability of a product being contaminated with visible debris after sterilization
   C. The amount of time it takes to complete a sterilization cycle
   D. The amount of heat and pressure required for a successful sterilization cycle
475. Which type of glass is suitable for packaging of non-parenteral products?
   A. Type I glass B. Type III glass C. Type II glass D. Type IV glass
476. Purpose of conducting APS in sterile manufacturing facility is
   A. To validate or evaluate the capability of aseptic processing activities, using growth promoting media in place of the product and/or equipment
   B. To assess changes made to an aseptic processing operation which might impact the sterility of the final product thereby to confirm state of control.
   C. To evaluate proficiency of personnel and identify weaknesses which might contribute to the microbiological contamination of the product
   D. To provide a measure of the probability of microbiological contamination arising in particular aseptic processes.
   E. To demonstrate appropriateness of operating practices used in support of aseptic processing.
   F. All

477. What is the ideal steam quality for most applications?

A. 100% B. 90% C. 80% D. 70%

478. What action needs to be taken for failure of APS when the batches are already filled?

A. Review all batches produced before failure and after failure and assessed after the investigation of the failed APS.
B. Review of the failed APS make to investigate/ identify root cause and propose corrective action
C. After corrective action implementation, redo APS with the necessary number of batches with at least 3 batches
D. All commercial batches produced before the failure and after the failure needs to be quarantined and investigated and make decision based on risk assessment.
E. All are true statements that should be considered during APS failure.

479. What is the typical incubation time for a BIs test?

A. 24 hours B. 48 hours C. 72 hours D. It depends

480. What is the purpose of a change control system in a pharmaceutical quality system?

A. To manage changes to processes, equipment, facilities, and systems to ensure that they are controlled and do not adversely affect product quality
B. To comply with regulatory requirements
C. To reduce manufacturing costs
D. To maximize profits for the company

481. Who is responsible for initiating a CAPA process?

A. Quality control department C. Management
B. Employees who identify the problem D. All of the above

482. Which factor affects steam quality the most?

A. Temperature B. Pressure C. Moisture content D. Volume

483. Which approach of microbiological validation is/are recognized for the examination and establishment of an acceptable dose range for the intended sterilization cycle

A. Fraction-negative experimental cycles
B. Survival kill experimental cycles
C. Bioburden experimental cycles
D. BIs experimental cycles

484. Which of the following statements is/are **CORRECT** regarding environmental monitoring?
   A. Settle plates used to measure atmospheric contamination are normally exposed for 24 hours
   B. Settle plates are the only means by which atmospheric contamination can be monitored
   C. Skin scales shed by the operators are the most potent source of microbial contamination in a microbiological clean room
   D. The small diameter Petri dishes used to pick up microbial contamination from solid surfaces are called rotary plates
   E. Sampling of different areas of exposed skin, exhaled air and clothing for microbial contamination is a routine part of an environmental monitoring programme
485. Which of the following statements regarding sterility tests is/are **CORRECT**?
   A. An item cannot be guaranteed to be sterile
   B. An item which has failed a sterility test is certain to be contaminated
   C. An item that has passed a sterility test is certain to be sterile
   D. The sterile state does not ever exist
   E. Antibiotics are self-sterilizing so it is illogical to subject them to sterility testing
486. In a PhEur sterility test:
   A. Medical devices cannot be tested for sterility because they are insoluble
   B. Membrane filtration is the preferred method of conducting the test
   C. The method suitability test is primarily intended to confirm that any antimicrobial activity present in the sample has been adequately neutralized
   D. Negative controls should be incorporated in the testing procedure
   E. There is no option to repeat a failed valid test
487. Which of the following statements is **FALSE**?
   A. D value is the time in minutes required to reduce a population of microorganisms to 90% of its initial value.
   B. D value can be calculated from the slope of a survivor plot for a population of organisms dying according to first-order kinetics.
   C. Z value indicates the extent to which a change in temperature alters the death rate of a population of cells being killed by heat.
   D. Z value is defined as the number of degrees Celsius temperature change required to produce a 10-fold change in the D value.

488. What is the purpose of environmental monitoring in a cleanroom?
    - A. To detect and quantify the presence of particulate matter and microorganisms in the air and on surfaces
    - B. To measure temperature and humidity levels
    - C. To track employee productivity
    - D. To comply with regulatory requirements
489. Which one is **NOT** a recommended practice for maintaining a cleanroom?
    - A. Using appropriate cleaning agents and disinfectants
    - B. Minimizing personnel traffic in the cleanroom
    - C. Storing non-essential equipment and materials in the cleanroom
    - D. Regularly inspecting and maintaining cleanroom equipment and systems
    - E. None
490. What is the primary purpose of BIs?
    - A. To measure temperature and humidity levels
    - B. To detect and quantify particulate matter in the air
    - C. To detect and quantify microorganisms in a sterilization process
    - D. To track employee productivity
491. What should the manufacturer's PQS ensure in relation to sterile products manufactured?
    - A. Proper container integrity
    - B. Regulatory compliance
    - C. Sterility test failures
    - D. Sufficient knowledge and expertise
492. A statistically based design of experiment (DoE) approach can be helpful during which stage of the process validation and involves defining a process for manufacturing.
    - A. Process design
    - C. Pilot scale up manufacturing
    - B. Process performance qualification
    - D. Continued process verification
493. What is the purpose of a spore log reduction in a BIs test?
    - A. To document the results of each individual test
    - B. To track employee productivity
    - C. To comply with regulatory requirements
    - D. To provide a long-term record of the sterilization process over time

494. Which of the following is correction/remedial action?
    - A. Replacing the label on a device that had the wrong label applied
    - B. Revising process parameters in response to complaints
    - C. Rewelding a contact that does not meet visual inspection requirements
    - D. Auditing all vendors of a key component after quality issues are identified
    - E. A and C
495. Procedures for cleaning of sampling tools should be ____________ and included in the cleaning validation master plan except for the ones, which are dedicated or disposable.
    - A. Validated
    - C. Written
    - B. Confidential
    - D. Developed
496. What type of microorganism is commonly used in BIs?
    - A. E. coli
    - B. S. aureus
    - C. Bacillus subtilis
    - D. Salmonella
497. Which one is **NOT** a common use for BI in the healthcare industry?
    - A. Monitoring sterilization processes in hospitals and clinics
    - B. Monitoring cleaning and disinfection processes in healthcare facilities
    - C. Monitoring hand hygiene compliance among healthcare workers
    - D. BIs are used for all of these purposes
498. What is the acceptable range for steam quality in industrial applications?
    - A. 0-10%
    - B. 10-25%
    - C. 25-50%
    - D. 95-100%
499. Any water for use in general cleanup in noncritical areas is typically treated, while water used in critical operation rooms is sterilized
    - A. True
    - B. False
500. Which one is **NOT** a factor that can affect the accuracy of a BI test?
    - A. Improper storage or handling of the BIs
    - C. Contamination of the test environment
    - B. Variability in the sterilization process
    - D. The brand of BIs being used
501. What is lyophilization?
    - A. Process of sterilizing equipment
    - C. Process of freeze-drying a product
    - B. Process of terminal sterilization
    - D. Process of aseptic processing
502. What happens if the steam quality is too low?
    - A. Equipment can be damaged
    - C. Efficiency is reduced
    - B. Corrosion can occur in pipelines
    - D. All of the above

503. What is a requalification in cleaning validation terms?
    A. The process of repeating cleaning validation testing after a significant change has been made to a manufacturing process
    B. The process of repeating cleaning validation testing on a regular basis to ensure ongoing compliance
    C. The process of repeating cleaning validation testing after a minor change has been made to a manufacturing process
    D. The process of repeating cleaning validation testing only when required by agencies
504. What is the purpose of sterile manufacturing?
    A. To prevent contamination of pharmaceutical products
    B. To increase shelf life of pharmaceutical products
    C. To improve taste and appearance of pharmaceutical products
    D. All of the above
505. What is the primary benefit of maintaining high steam quality?
    A. Improved efficiency
    B. Increased safety
    C. Reduced maintenance costs
    D. All of the above
506. What should be annually reviewed during the review period of a product process and/or its manufacturing process of any and every product that have been produced?
    A. Starting and packaging materials status especially those from new sources.
    B. Supply chain traceability
    C. Critical in-process controls and finished product results
    D. OOS batches, deviations and batches that failed and the effectiveness of previous and current CAPA
    E. All
507. What is the most common method used for steam quality testing?
    A. Calorimeter
    B. Flow meter
    C. Pressure gauge
    D. Thermometer
508. What is the primary challenge in maintaining sterility during manufacturing?
    A. Ensuring equipment is properly cleaned and sterilized
    B. Controlling environmental factors
    C. Training personnel on aseptic technique
    D. All of the above

509. Which one is **NOT** a type of sterile manufacturing?

A. Aseptic processing
C. Terminal sterilization
B. Non-sterile processing
D. Isolator technology

510. What does methods should be validated on qualified systems mean?

A. Qualification shows a system performs as the vendor intended
B. Qualification is not intended as a complete re-validation of the design and it does not demonstrate suitability for intended use
C. Qualification is to provide documented evidence of proper system performance in terms of accuracy, linearity and precision
D. Method validation shows suitability of a system to perform a specific analysis

511. What is the purpose of a data audit trail?

A. To track changes made to data over time
B. To prevent unauthorized access to data
C. To encrypt data to protect it from hackers
D. To ensure that data meets certain criteria or standards
E. All

512. How should risk management be applied in the development and maintenance of the CCS?

A. By increasing residual risk
C. By reducing contamination risks
B. By excluding root cause analysis
D. By minimizing product quality review

513. During which stage of the process validation cGMP-compliant procedures are commenced and must be followed.

A. Process design
C. Pilot scale up manufacturing
B. Process performance qualification
D. Continued process verification

514. What is the purpose of adding a cryoprotectant to the product before freezing?

A. To prevent contamination during freezing
B. To protect the product from damage during freezing
C. To improve the taste and appearance of the product
D. A and C

515. What is the first step in the lyophilization process?

A. Freezing the product
C. Adding cryo agent to the product
B. Sterilizing the product
D. Pretreatment or Formulation

516. For final filtration, when is the right time to test the integrity of the filter before use or before or after or during sterilization?
   A. The integrity testing should be done after sterilization as filter properties may have been impacted by sterilization and there may be some flexibility for early-stage sterile filtration
   B. The integrity testing should be done before sterilization as filter properties may be impacted by sterilization and there may be some flexibility for later-stage sterile filtration
   C. The integrity testing should be done during sterilization as filter properties may impact the sterilization and there may not be flexibility for at any stage sterile filtration
   D. A and B
517. During hazard identification stage of QRM process, what is the need to collect information from different sources such as historical data, theoretical analysis and others
   A. To identify potential sources of the hazard
   B. To determine how frequently a hazard occurs.
   C. To estimate the risk using RPN
   D. A and B
518. What are the ideal acceptance criteria for an aseptic media fill?
   A. No growth in any unit tested
   B. < 5% growth in any unit tested
   C. < 1% growth in any unit tested
   D. None of the above
519. What is the purpose of lyophilization?
   A. To increase the shelf life of a product
   B. To improve the taste and appearance of a product
   C. To prevent contamination of a product
   D. All of the above
520. What is steam quality?
   A. The temperature of steam
   B. The pressure of steam
   C. The amount of moisture in steam
   D. The volume of steam
521. What is the purpose of an aseptic media fill?
   A. To test the sterility of the manufacturing process
   B. To increase the shelf life of a product
   C. To improve the taste and appearance of a product
   D. All of the above

522. The identified risk can be reduced to acceptable level in QRM process by
    - A. Increasing chances of detection thereby eliminating hazard
    - B. Decreasing both severity and probability of occurrence
    - C. Changing process by implementing SOP's with appropriate documentation
    - D. Providing training and performing appropriate review
    - E. All
523. Aseptic media fill is a process of ____________
    - A. Sterilizing equipment
    - C. Filling a product with sterile media
    - B. Terminal sterilization
    - D. Aseptic processing
524. Which one is **NOT** a factor that can affect sterility of a product?
    - A. Temperature
    - B. Pressure
    - C. Humidity
    - D. Time
525. The action level or permissible exposure limit for EtO exposure during aeration stage according to OHSA is
    - A. 0.5 ppm/8hrs
    - B. 5 ppm/1min
    - C. 1 ppm
    - D. 0.05ppm/8hrs
526. Which one is **NOT** a common source of contamination in sterile manufacturing?
    - A. Personnel
    - B. Equipment
    - C. Raw materials
    - D. Air
527. What should persons responsible for certification/release of sterile products have?
    - A. Regulatory compliance expertise
    - B. Access to manufacturing and quality information
    - C. Basic knowledge of risk management
    - D. Experience in root cause analysis
528. What is the purpose of incubating the filled product?
    - A. To test for contamination
    - C. To improve assurance of product
    - B. To sterilize the product
    - D. None of the above
529. What is the phase one maximum acceptable level of conductivity in µS/cm for WFI?
    - A. 1.3
    - B. 2.1
    - C. 3.3
    - D. 4.7
530. What is the purpose of performing a positive control in an aseptic media fill?
    - A. To ensure that the media is sterile before filling
    - B. To validate the testing method for contamination
    - C. To test for endotoxins in the product
    - D. None of the above

531. Which one is a benefit of change control?

A. Improved product quality
B. Increased efficiency
C. Reduced risk of errors or defects
D. All of the above

532. What is the purpose of a media fill validation?

A. To optimize the aseptic media fill process for a specific product
B. To validate the aseptic media fill process
C. To test for endotoxins in the product
D. None of the above

533. Containers should be immediately re-sealed after sampling to avoid ____________.

A. Theft
B. Cross contamination
C. Mix-up
D. Wastage

534. What is the purpose of water for injection (WFI)? To be used as a

A. Solvent for injections
B. Carrier for injections
C. Diluent for injections
D. None of the above

535. The percentage recirculated air should be determined be based on

A. Sufficient fresh air to compensate for leakage from the facility
B. Sufficient fresh air to compensate for loss through exhaust air systems
C. Sufficient fresh air for odor control
D. Sufficient fresh air to provide the required building pressurization.

536. What air classification should solutions being prepared prior to filtration be located (EU)?

A. Grade C
B. Grade A
C. Grade B
D. Grade D

537. What is the difference between validation and verification of a sterilization process?

A. Validation ensures that a process is capable of consistently producing sterile products, while verification confirms that a specific batch of products has been sterilized.
B. Validation confirms that a specific batch of products has been sterilized, while verification ensures that a process is capable of consistently producing sterile products.
C. Validation and verification are the same thing.
D. None of the above.

538. All sampling techniques for each specific product type must be addressed in _______.

A. Batch document
B. Written procedures
C. Master formula
D. Sampling plan

539. Who is responsible for initiating a change control request?

A. The quality assurance department

B. The manufacturing department

C. Any employee who identifies a need for a change

D. None of the above

540. Which factor can affect the accuracy of a steam quality test?

A. Ambient temperature

B. Pressure fluctuations

C. Humidity

D. All of the above

541. **TRUE** statement about process validation

A. Process validation data should be generated for all products, to demonstrate the adequacy of the manufacturing process.

B. Homogeneity within a batch and consistency between batches are goals of process validation activities.

C. Process validation continues till the product shelf life in the market to provide assurance of a finished product even after its dispatch to the market.

D. Process validation is implemented when there are no documents for its manufacturing and testing of a new product

E. All

542. What is the purpose of a change control plan?

A. To outline the steps involved in implementing a change

B. To identify potential risks and mitigation strategies

C. To specify roles and responsibilities for implementing a change

D. All of the above

543. What is the first step in change control?

A. Identifying the need for a change

B. Implementing the change

C. Evaluating the impact of the change

D. Investigating root cause for a change

544. What is an effectiveness check in CAPA?

A. A process of monitoring whether the CAs were implemented correctly.

B. A process of monitoring whether the CAs solved the problem.

C. A process of monitoring whether the PAs are effective.

D. None of the above.

545. How often should a CAPA process be reviewed?

A. Monthly
C. Quarterly
B. Annually
D. Half a year

546. What tests should be conducted prior to filtration sterilization according to EU?

A. Bioburden and filter integrity testing
C. Bioburden and endotoxin testing
B. Endotoxin and Sterility testing
D. Pressure decay testing

547. What is the purpose of terminal sterilization?

A. To eliminate all microorganisms from a product
B. To reduce the number of microorganisms in a product
C. To prevent the growth of microorganisms in a product
D. None of the above

548. What is the minimum acceptable temperature for WFI storage?

A. 2°C
B. 4°C
C. 6°C
D. 8°C

549. All microbiological laboratories need to have a procedure to test the total number of microorganisms and to assess the absence of specific ____________.

A. Contaminants
C. Bacterial species
B. Impurities
D. Ingredients

550. What is a sterility assurance level (SAL)?

A. The probability of a product being non-sterile after sterilization.
B. The probability of a product being sterile after sterilization.
C. The probability of a product being contaminated during sterilization.
D. None of the above.

551. The use of bisulfite in pharmaceutical water system is

A. To chemically reduce chlorine to chloride and protect downstream equipment
B. To chemically oxidize chloride to chlorine and protect downstream equipment
C. To chemically reduce chlorine to chloride and protect upstream equipment
D. To chemically oxidize chloride to chlorine and protect upstream equipment

552. Samples should always be done by ____________ personnel who are not only designated to pull samples but are also appropriately trained.

A. Senior and experienced
C. Specific and authorized
B. New and fresh
D. Production

553. For ISO Level 2 protection, which filter grade is recommended for protected area operating with return air

   A. EN 799 G-4 plus EN 1822 F8 or F9

   B. EN 799 G-4 plus F-8 or F9 and EN 1822-H13

   C. EN 799 G-5 plus F-5 or F7 and EN 1822-H14

   D. EN 799 G-4 plus EN 1822 F6 or F7

554. What is the purpose of a sterility test?

   A. To confirm that a product is sterile after sterilization.

   B. To confirm that a product is non-sterile after sterilization.

   C. To confirm that a product has been exposed to sterilization conditions.

   D. None of the above.

555. What is a BIs?

   A. A device used to measure the temperature and pressure during sterilization.

   B. A device used to monitor the humidity level during sterilization.

   C. A device containing a known population of microorganisms used to confirm the effectiveness of sterilization.

   D. None of the above.

556. What is the role of quality control in terminal sterilization?

   A. To ensure that the sterilization process is validated and verified.

   B. To ensure that the appropriate methods and parameters are used for sterilization

   C. To ensure that the appropriate documentation is maintained.

   D. All of the above.

557. In order to implement a successful stability program, a procedure should be available to place at least one lot of each product/package on ____________ each year.

   A. Annual review B. Stability C. Re-Validation D. Testing

558. Filling and sealing of the ampules take place in which clean room class_____

   A. Class C B. Class A C. Class B D. Class D

559. The method used for demonstrating the ability of culture media to support the growth of microorganisms is called ____________.

   A. Sterility test C. Process simulation test

   B. Growth promotion test D. Filter integrity test

560. The items to be sterilized should be wrapped in a material
    - A. To allows the removal of air and the penetration of steam but prevents recontamination after sterilization.
    - B. To test for air-tight integrity of pre-vacuum autoclave chamber and plumbing system
    - C. To assure that level of assurance, regardless of the number and the heat resistance
    - D. To verify that the steam supply assures product sterility.
561. What is the difference between sterilization and disinfection?
    - A. Sterilization eliminates, while disinfection reduces their numbers.
    - B. Sterilization uses chemicals, while disinfection uses heat.
    - C. Sterilization is used for surfaces, while disinfection is used for products.
    - D. None of the above.
562. Which one is **NOT** a requirement for successful process validation?
    - A. Clear and concise validation protocol
    - B. Qualified personnel
    - C. Robust manufacturing process
    - D. Inadequate documentation
563. What is the first stage of process validation according to FDA?
    - A. Process design
    - B. Continued process verification
    - C. Process qualification
    - D. Process monitoring
564. What is the purpose of aseptic technique?
    - A. To prevent contamination during the manufacturing process.
    - B. To ensure that all products are sterile.
    - C. To reduce the number of living organisms in the environment.
    - D. None of the above.
565. What is the recommended method for WFI sterilization?
    - A. Filtration using 0.22 μm filter
    - B. Gamma irradiation
    - C. Autoclaving at 121°C for 30 minutes
    - D. None of the above
566. When the system, utility or equipment is received at the end user, tests should be performed
    - A. To verify the acceptability of the system, utility or equipment.
    - B. To ensure that the system, utility or equipment is appropriate and ready for dispatch.
    - C. To ensure that the system operates according to the described specifications
    - D. To ensure that the equipment which gives acceptable results without load will produce the same results under load.

567. During at rest, oral liquid Manufacturing area is__________

A. Class D B. Class B C. Class A D. Class C

568. What is a root cause analysis?

A. A process of identifying the underlying causes of a problem.
B. A process of identifying the symptoms of a problem.
C. A process of implementing corrective actions.
D. None of the above.

569. What is the requirement for validation of glass container depyrogenation (FDA)?

A. 3-log reduction in endotoxin challenge C. 6-log reduction in endotoxin challenge
B. 4-log reduction in endotoxin challenge D.12-log reduction in endotoxin challenge

570. What is the maximum acceptable level of endotoxins (EU/ml) in WFI?

A. <0.05 B. <0.1 C. <0.25 D. <0.5

571. Materials which are more susceptible to contamination, should be sampled in____ area.

A. Open area B. Controlled area C. Cold area D. Quarantine area

572. What is the difference between a BIs and a chemical indicator?

A. BIs contains microorganisms, while a chemical indicator changes color when exposed to sterilization conditions.
B. BIs changes color when exposed to sterilization conditions, while a chemical indicator contains microorganisms.
C. BIs and a chemical indicator are the same thing.
D. None of the above.

573. When should a CAPA process be closed?

A. When the corrective actions have been implemented
B. When the effectiveness check has been completed
C. When management approves the closure
D. All of the above

574. What type of information is typically included in a Type II DMF?

A. Manufacturing process and controls for the drug product
B. Analytical methods and specifications for the drug product
C. Stability data and storage conditions for the drug product
D. All of the above

575. What are some challenges associated with implementing parametric release?

A. Resistance to change from traditional sterility testing methods.

B. Difficulty in establishing appropriate parameters for release.

C. Regulatory requirements for sterility testing.

D. All of the above.

576. What is the purpose of a lyophilization cycle development?

A. To optimize the process

C. To validate the process

B. To test for endotoxins in the product

D. None of the above

577. What is the purpose of a laminar flow hood?

A. To provide a sterile environment for product preparation.

B. To reduce the number of living organisms in the environment.

C. To disinfect surfaces before product preparation.

D. None of the above.

578. How is parametric release different from traditional sterility testing?

A. Parametric release relies on physical and chemical parameters, while traditional sterility testing relies on microbial growth.

B. Parametric release is more time-consuming than traditional sterility testing.

C. Parametric release requires more resources than traditional sterility testing.

D. None of the above.

579. What are the key parameters for parametric release?

A. Temperature, time, and pressure.

C. pH, conductivity, and viscosity.

B. Moisture content, particle size, and color.

D. None of the above.

580. What is a sterile barrier?

A. A physical barrier that separates the aseptic environment from the non-aseptic environment.

B. A chemical barrier that kills living organisms.

C. A barrier that prevents the growth of bacteria.

D. None of the above.

581. Approval signatures on electronic documents

A. Electronic or hard copy as appropriate.

C. Must always be written by hand.

B. Are not required at all.

D. Must always be electronic.

582. What is the purpose of process monitoring?
    - A. To demonstrate that the manufacturing process is capable of consistently producing products that meet their intended specifications and quality standards.
    - B. To optimize the manufacturing process for maximum efficiency.
    - C. To monitor and control the manufacturing process in real-time.
    - D. None of the above.
583. What are the common methods of terminal sterilization?
    - A. Ethylene oxide
    - B. Steam sterilization
    - C. Gamma irradiation
    - D. All of the above
584. What is the role of process validation in parametric release?
    - A. To ensure that the manufacturing process is capable of consistently producing products that meet the required parameters.
    - B. To ensure that the products are free from microbial contamination.
    - C. To ensure that the products are visually inspected for defects.
    - D. None of the above.
585. What is the purpose of sublimation during lyophilization?
    - A. To remove moisture from the product
    - B. To sterilize the product
    - C. To add moisture to the product
    - D. None of the above
586. For dry heat or depyrogenation processes, which type of thermocouples are used
    - A. Type T and Type J are used.
    - B. Type J and Type B are used.
    - C. Type K and Type J are used.
    - D. Type N and Type E are used.
587. What is a dose audit?
    - A. Process of measuring the amount of radiation used during gamma irradiation.
    - B. Process of measuring the amount of ethylene oxide gas used during sterilization.
    - C. Process of measuring the amount of time and temperature used during steam sterilization.
    - D. None of the above.
588. What are the benefits of parametric release?
    - A. Faster release times for products.
    - B. Reduction in costs associated with sterility testing.
    - C. Increased efficiency in manufacturing processes.
    - D. All of the above.

589. One of the following is **NOT** an activity carried out during OQ?
   - A. Critical operating parameters and facility operations should be identified and SOPs are finalized and approved.
   - B. Training of operators for the systems, utilities and equipment
   - C. Low medium and high ranges, upper and lower operating limits, including “worst case” conditions are verified.
   - D. Test is performed without load and different operational ranges in empty or as built conditions with supplies and connections.
   - E. Test is performed with load and same operational ranges mimicking routine operational conditions with supplies and connections.
590. The filtration process should be complemented by some degree of heat treatment (EU)?
   A. True B. False
591. Which changes would require change control?
   - A. Changing the color of a product label
   - B. Ordering new office supplies
   - C. Changing the manufacturing process for a product
   - D. None of the above
592. Which one is a benefit of lyophilization?
   - A. Increased stability of the product
   - B. Shorter production time
   - C. Reduced cost of production
   - D. All of the above
593. What is the purpose of statistical process control in parametric release?
   - A. To monitor the manufacturing process, detect any changes or trends, and ensure that it remains within specified parameters.
   - B. To ensure that all products are sterile.
   - C. To ensure that all products meet visual inspection criteria.
   - D. None of the above.
594. What are some challenges associated with aseptic sterilization?
   - A. Maintaining a sterile environment.
   - B. Ensuring that all equipment and materials are properly sterilized.
   - C. Meeting regulatory requirements for sterility testing.
   - D. All of the above.

595. What is analytical method validation?
   A. The process of testing a method to ensure its accuracy, precision, and reliability.
   B. The process of verifying the identity of a sample.
   C. The process of determining the purity of a sample.
   D. None of the above.

596. During which stages of qualification, a pharmaceutical manufacturer should establish action level and alert level for water system?
   A. Installation B. Operational C. Performance D. Design

597. A successful completion of OQ should allow the finalization of tasks such as
   A. Standard operating procedure (SOP) are available.
   B. Cleaning procedures and Operator training
   C. Preventative maintenance requirements
   D. Permit a formal "release" of the facilities, systems and equipment.
   E. All

598. What is range in analytical method validation?
   A. The concentration range over which the method can produce accurate and precise results.
   B. The number of samples that can be analyzed using the method.
   C. The time required to perform the analysis using the method.
   D. None of the above.

599. Dehumidification in the air handling unit mainly works by
   A. Heating or cooling mechanism C. Rotating silica beads wheel.
   B. Using a shower of water. D. A and B

600. What is the recommended storage period for WFI in bulk containers?
   A. 24 hours B. 48 hours C. 72 hours D. 96 hours

601. What is the acceptable range for dryness fraction in high-pressure steam?
   A. 0-5% B. 5-10% C. 10-15% D. 15-20%

602. What is the purpose of accuracy in analytical method validation?
   A. To ensure that the method measures what it is supposed to measure.
   B. To ensure that the method is precise.
   C. To ensure that the method is robust.
   D. None of the above.

603. SAT is test conducted at the vendor's premises to verify that the system, equipment or utility, as assembled or partially assembled, meets expected specifications

A. True B. False

604. **FALSE** statement about ICH Q10

A. It is the interpretation and application of cGMP regulations to the operation.
B. It is an integrated system of documentation with increasing specificity from the quality policy and quality standards down to the sop, and other executable work instructions.
C. It is optional and will only be operational and sustainable the moment its documents become effective.
D. Enhance the quality and availability of medicines globally in the interest of public health.
E. The regional GMP does address the system the product lifecycles needed to bring a quality product to market.

605. CAPA effectiveness check is mainly done at which stage of QRM process?

A. Risk Review
B. Risk Control
C. Risk Communication
D. Risk Identification

606. What are the key parameters evaluated during analytical method validation?

A. Accuracy, precision, specificity, linearity, range, and robustness.
B. Sensitivity, selectivity, purity, stability, and reproducibility.
C. Calibration, standardization, normalization, and quantification.
D. None of the above.

607. What is a potential consequence of inspection deficiency?

A. Increased profits
B. Decreased employee morale
C. Increased regulatory oversight
D. Increased customer satisfaction

608. All activities related to sampling, storage, assignment to analyst, testing, results documenting, retention and finally ____________ should be performed as per approved procedure.

A. Release of sample
B. Stability study of sample
C. Destruction of sample
D. Validation study

609. Which type of sterilization involves the use of high pressure and temperature?

A. Autoclaving
B. Gamma irradiation
C. Ethylene oxide sterilization
D. Dry heat sterilization

610. Where a system, utility or equipment is assembled, or partially assembled at a site other than that of the purchaser or end-user, testing and verification should be done and recorded
   A. To ensure that the system, utility or equipment is appropriate and ready for dispatch.
   B. To verify the acceptability of the system, utility or equipment.
   C. To ensure that the system operates according to the described specifications
   D. To ensure that the equipment which gives acceptable results without load will produce the same results under load.
611. All of the following are **TRUE** about both IQ.
   A. Verification of the MOC, safety features, proper installation and occupying space
   B. Verification all the cleaning methods, cables and connectors
   C. Collection and collation of supplier operating or reference manuals and drawing
   D. Gathering the SOP and maintenance requirements of the systems
   E. All
612. What is the purpose of precision in analytical method validation?
   A. To ensure that the results are consistent and reproducible.
   B. To ensure that the method is accurate.
   C. To ensure that the method is specific.
   D. None of the above.
613. What is stability in analytical method validation?
   A. The ability of the sample to remain unchanged over time.
   B. The ability of the method to produce consistent results over time.
   C. The ability of the equipment to maintain its calibration over time.
   D. None of the above.
614. What is the most common method for container closure integrity testing?
   A. Microbial challenge testing C. Visual inspection
   B. Leak testing D. Sterility testing
615. What are some common challenges associated with analytical method validation?
   A. Variability in sample matrix.
   B. Interference from impurities or other analytes.
   C. Limited availability of reference standards or certified reference materials.
   D. All of the above.

616. What is process validation?
   A. Ensuring that a product meets its intended specifications and quality standards.
   B. The process of verifying the identity of a product.
   C. The process of determining the purity of a product.
   D. None of the above.
617. All regulatory agencies have emphasized on the significance of ____________ which makes it a critical component of GMP.
   A. Accelerated stability study C. Stability study
   B. Humidity and temperature D. Data collection
618. Which one is a class II recalled product according to FDA recall system?
   A. Life-saving medication with labelling mix-up
   B. A drug that is with low strength but not used to treat life threatening situation
   C. A minor container defects
   D. Package labelling not written in English language
619. If a change is proposed to existing process that may affect product quality or ____________ of the process, change control must be initiated.
   A. Authenticity C. Reproducibility
   B. Speed D. Total expenses
620. Recirculation of air within a ventilation system without appropriate efficient filtration
   A. Is an unacceptable practice and should be stopped by all GMP inspectors.
   B. Is the only economic option and may be used in all facilities.
   C. Will affect the operations that can be carried out in that area.
   D. Depends on the local health and safety rules.
621. Which one is a non-destructive method of container closure integrity testing?
   A. Burst test B. Vacuum decay C. Dye ingress D. Microbial ingress
622. What is the purpose of process qualification in process validation?
   A. To demonstrate that the manufacturing process is capable of consistently producing products that meet their intended specifications and quality standards.
   B. To develop new manufacturing processes for novel products.
   C. To improve the efficiency of existing manufacturing processes.
   D. None of the above.

623. What are some common challenges associated with process validation?

A. Variability in raw materials and equipment.

B. Lack of understanding of the manufacturing process.

C. Difficulty in establishing appropriate acceptance criteria.

D. All of the above.

624. What is the primary benefit of using isolator technology in sterile manufacturing?

A. Improved operator safety

B. Increased efficiency

C. Reduced risk of contamination

D. All of the above

625. **FALSE** about the selection of the nutrient medium in APS processing

A. Dosage form of the product like liquid or solid

B. High selectivity of the growth medium

C. Clarity, concentration of the growth medium

D. Suitability for sterilisation of the nutrient medium

626. Which one is **NOT** a method of aseptic processing?

A. Barrier systems

B. Cleanrooms

C. Isolator technology

D. Terminal sterilization

627. What is the purpose of process control?

A. To establish the parameters and criteria for the manufacturing process.

B. To improve the efficiency of the manufacturing process.

C. To monitor and control the manufacturing process in real-time.

D. None of the above.

628. What is the purpose of environmental monitoring in aseptic sterilization?

A. To ensure that the environment is free from living organisms.

B. To detect any contamination events.

C. To ensure that all products are sterile.

D. None of the above.

629. What is the purpose of container closure integrity (CCI) testing?

A. To ensure the CCI system can maintain the sterility of the product.

B. To ensure the CCI system can protect the product from contamination.

C. To ensure the CCI system can maintain the product's stability and efficacy.

D. All of the above.

630. What is the purpose of a media fill test?

A. To determine if a product is sterile
B. To test for endotoxins in a product
C. To validate the aseptic processing
D. All of the above

631. What is the most common method for filter integrity testing?

A. Bubble point test
B. Water intrusion test
C. Diffusion test
D. Pressure hold test

632. Which one of the following discrepancies shall be **NOT** dealt as incident deviation?

A. Temporary power failure in a warehouse where no temperature sensitive materials are stored, with no temperature excursion from the established range.
B. Environmental monitoring data reach alert levels but are still within acceptable range.
C. Production process parameters reach alert levels but are still within acceptable range.
D. Untrained personnel responsible for segregating the approved and rejected raw material in the warehouse
E. A and B

633. What is the process of identifying and assessing potential risks in the cleanroom environment called?

A. Risk management
B. Change control
C. Quality risk management
D. Quality system

634. What is the purpose of continued process verification in process validation?

A. To monitor and control the manufacturing process in real-time to ensure that it remains within established parameters and criteria.
B. To optimize the manufacturing process for maximum efficiency.
C. To develop new manufacturing processes for novel products.
D. None of the above.

635. Which one is a non-destructive method of container closure integrity testing?

A. Helium leak test
B. Tracer gas-Sniffer test
C. Dye-ingress test
D. Pressure hold test

636. In extremely cold conditions, by which mechanism does pharmaceutical companies require to add some humidity in the processed air,

A. Using a shower of water.
B. By evaporation of water.
C. Heating or cooling mechanism
D. A and B

637. What is robustness in analytical method validation?
    A. The ability to produce accurate and precise results under different conditions.
    B. The ability of the method to detect impurities in the sample.
    C. The ability of the method to separate different analytes in the sample.
    D. None of the above.
638. The purpose of vacuum leak test method is?
    A. To test for air-tight integrity of pre-vacuum autoclave chamber and plumbing system
    B. Allows the removal of air and the penetration of steam but prevents recontamination
    C. To verify that the steam supply assures product sterility.
    D. To assure that level of assurance, regardless of the number and the heat resistance
639. What is the most commonly used parameter for measuring steam quality?
    A. Temperature B. Pressure C. Enthalpy D. Dryness fraction
640. What is the regulatory requirement for container closure integrity testing?
    A. It is not required by any regulatory agency.
    B. It is only required for sterile products.
    C. It is required for all products, but the method is not specified.
    D. It is required for all products, and the method must be validated.
641. What is the recommended frequency for testing steam quality?
    A. Weekly B. Monthly C. Quarterly D. Annually
642. What is a Critical operation?
    A. A process that may cause variation in the quality of the pharmaceutical product.
    B. A process that cannot be controlled.
    C. A process that has consistent product.
    D. None of the above.
643. What is the purpose of filter integrity testing?
    A. To ensure the filter is free of defects and can effectively remove contaminants.
    B. To ensure the filter can withstand the pressure of the process.
    C. To ensure the filter can maintain its shape and size.
    D. None of the above.
644. Which of the following ICH guidelines addresses the elemental impurities?
    A. ICH Q2(R1) B. ICH Q3B C. ICH Q3C D. ICH Q3D

645. The objective/s of commercial manufacturing activities are
    A. Achieving product realization, establishing and maintaining a state of control, and facilitating continual improvement.
    B. Establish a commercial manufacturing process capable of consistently producing a product with its intended quality.
    C. Process performance is achieved, improvement opportunities are identified and evaluated, and the body of knowledge is continually expanded
    D. A and B
646. What is the maximum allowable particle size for ISO Class 7 cleanroom?
    A. 0.5 µm B. 1µm C. 5µm D. 10 µm
647. The purity attributes for pure steam are measured in the condensate of the article, rather than the article itself.
    A. True B. False
648. Starting materials may be used
    A. Once they have been sampled by the quality control department.
    B. Immediately after they have been labeled with all the details about receipt.
    C. Only when released by the quality control department and within their shelf-life.
    D. Immediately after the purchasing section has paid the supplier's invoice.
649. On receipt; starting materials
    A. Should be checked to ensure that the consignment corresponds to the order.
    B. If found to have broken seals, can be accepted so long as the delivery driver states that all is well.
    C. If made up of different batches of the same material, can be sampled as though they are all one batch.
    D. Do not need to be labeled until passed by the quality control department.
650. Which one is **NOT** a factor that can affect steam quality?
    A. Boiler pressure C. Feedwater temperature
    B. Steam flow rate D. Ambient humidity
651. Which one is **NOT** a commonly used filter material?
    A. Cellulose acetate C. Nylon
    B. Stainless steel D. Polyethersulfone

652. During product lifecycle stages of PQS; the goal of pharmaceutical development is
   - A. To design a product and its manufacturing process to consistently deliver intended performance and meet the needs of patients, healthcare professionals, and NRA, and internal customers' requirements.
   - B. To transfer product and process knowledge between development and manufacturing and within or between manufacturing sites to achieve product realization.
   - C. To achieve product realization, maintaining a state of control, and facilitating continual improvement.
   - D. To establish a commercial manufacturing process capable of consistently producing a product with its intended quality.
653. What is the recommended exposure time for ethylene oxide gas sterilization?
   A. 30 min B. 1 hr. C. 4 hrs. D. 24 hrs.
654. Which one of the following discrepancies shall **NOT** be dealt as major deviation?
   - A. Untrained personnel responsible for segregating the approved and rejected raw material in the warehouse.
   - B. Logbook was not reviewed within specified time period.
   - C. Filter integrity test has been carried out using equipment with no documented installation qualification completed.
   - D. Pressure differential out of established limits in aseptic fill areas.
   - E. Operational parameter out of range for a parameter defined as non-critical.
655. Which one is a chemical indicator used to monitor sterilization?
   A. Temperature indicator C. Pressure indicator
   B. Biological Indicators D. Time indicator
656. What is the overall framework for ensuring that the cleanroom operates in a controlled and consistent manner?
   A. Risk management B. Quality system C. Change control D. All
657. What is the regulatory requirement for filter integrity testing?
   - A. It is not required by any regulatory agency.
   - B. It is only required for certain types of products.
   - C. It is required for all products, but the method is not specified.
   - D. It is required for all products, and the method must be validated.

658. All samples including the retention ones must be stored in containers meeting ____________ and specified storage conditions.

A. Regulatory requirements
C. Stability requirements
B. Quality requirements
D. Physical parameters

659. By which action existing nonconforming products may be initiated as reworking or reprocessing, repair, or adjustment of the product in order to disposition or eliminate the existing nonconformity and ensure that the product meets its specifications.

A. Corrections
C. Corrective action
B. Remedial action
D. A and B

660. Which one is **FALSE** statement about Blow Fill Seal equipment installed for aseptic sterilized production facility

A. It should be installed in at least a Grade C background environment.
B. It should be installed in at least a Grade D background environment.
C. Fitted with an effective Grade A air shower provided that Grade A or B clothing.
D. Grade C background with viable and non-viable limits both at rest and in operation

661. Annual product reviews process is established to determine the need for ____________ in drug products specifications, manufacturing or control procedures.

A. Validation B. Change C. Analysis D. Deviations

662. What are the exceptional circumstances in which concurrent validation can be utilized

A. When data from replicate production runs are unavailable because only a limited number of batches have been produced,
B. When batches are produced infrequently or batches are produced by a validated process that has been modified.
C. Where there is a strong benefit-risk ratio for the patient,
D. All

663. What is line clearance validation?

A. A process to ensure that all equipment and materials are removed from a production line before starting a new batch
B. A process to validate the cleaning of a production line before starting a new batch
C. A process to validate the calibration of equipment on a production line
D. A process to validate the packaging of a finished product on a production line

664. Who is responsible for performing line clearance validation?

A. Quality control department
B. Maintenance department
C. Production department
D. Marketing department

665. What is data integrity?

A. The security of data from unauthorized access
B. The accuracy and consistency of data over its entire lifecycle
C. The speed at which data can be accessed and processed
D. The amount of data that can be stored in a system

666. Which one is **NOT** a method of sterilization?

A. Autoclaving
B. Radiation sterilization
C. Ethylene oxide sterilization
D. Ultraviolet sterilization

667. What is the role of data validation in maintaining data integrity?

A. To ensure that data is not lost due to system failures
B. To prevent unauthorized access to data
C. To check that data meets certain criteria or standards
D. To encrypt data to protect it from hackers

668. Annual reviews should also include an executive summary of the product manufacturing experience during the ____________.

A. Manufacturing of first lot
B. Manufacturing of most recent lot
C. Review period
D. Shelf life

669. “Like for like” changes deemed to be implemented in which of the following cases?

A. Functionally equivalent equipment with exact replacements from the same manufacturer and with the same model and different ID number
B. Any exact component replacements that controls, monitors or records a critical process parameter from the same manufacturer and with the same model and ID number
C. Functionally equivalent equipment with exact replacements from different manufacturer, model and ID number
D. Any exact component replacements that directly transfers energy from the same manufacturer and with the same model and ID number
E. Any exact component or part replacements that contacts the product or primary packaging components

670. Which one of the following discrepancies shall **NOT** be dealt as minor deviation?
    A. Skip of FEFO principle (first expired-first out) in raw material handling.
    B. Balance out of tolerance used to determine gross weight of raw materials upon reception.
    C. Pressure differential out of established limits in class D washing area.
    D. Inadequately trained personnel to perform warehouse cleaning activities.
    E. Gross misbehavior of staff in a critical aseptic process.
671. Which methods can be used to measure steam quality?
    A. Thermocouples
    C. Pressure sensors
    B. Sampling and laboratory analysis
    D. All of the above
672. The type of HAVC filters required for different applications depends on
    A. The quality of the ambient air
    C. The return airs
    B. The air change rates.
    D. B and C
673. How can data backups help maintain data integrity?
    A. By preventing unauthorized access to data
    B. By ensuring that data is always available and accessible
    C. By providing a copy of the data in case of system failures or disasters
    D. By encrypting data to protect it from hackers
674. Which statement is **INCORRECT** about ICH Q10?
    A. It is intended to create new requirements for pharmaceutical manufacturing that go beyond those established in the current regulations, nor is the guidance intended to be a guide for the conduct of inspections.
    B. PQS elements serve as the major pillars that should be applied appropriately and proportionally across its lifecycle stages to identify areas for continual improvement.
    C. PQS enablers are pertinent throughout the lifecycle stages to support its scope or goals.
    D. The size and complexity of the company's activities should be taken into consideration when developing a new or modifying an existing quality system and its effectiveness is verified at manufacturing site level.
    E. An effective pharmaceutical quality system drives both supply chain robustness and sustainable GMP compliance.
675. How often should HVAC filters be replaced?
    A. Monthly
    B. Every 3 months
    C. Every 6 months
    D. Every year

676. What is the purpose of HVAC filters?

A. To improve indoor air quality
C. To reduce energy consumption
B. To increase equipment lifespan
D. All of the above

677. A ____________ must be established with scientific justification and statistical criteria such as confidence levels, component variability, degree of precision desired and the past history of supplier.

A. Master validation plan
C. Analytical method
B. Sampling plan
D. Final report

678. What types of particles can HVAC filters capture?

A. Dust and dirt
C. Pollen and pet dander
B. Mold spores and bacteria
D. All of the above

679. What is the outcome of a quality audit?

A. A report detailing any non-compliance issues and recommendations
B. A certificate of compliance
C. A financial penalty for non-compliance
D. A warning letter from regulatory agencies

680. What is the difference between an internal and external quality audit?

A. Internal audits are conducted by employees within the organization, while external audits are conducted by third-party auditors.
B. Internal audits are focused on compliance with regulations, while external audits are focused on production efficiency.
C. Internal audits are conducted annually, while external audits are conducted quarterly.
D. There is no difference between internal and external quality audits.

681. When should line clearance validation be performed?

A. Before starting a new batch
C. After finishing a batch
B. During production
D. By regulatory agencies

682. What are some common areas that are audited during a quality audit?

A. Production processes and equipment
B. Employee training and qualifications
C. Documentation and record-keeping practices
D. All of the above

683. What is the MERV rating of a filter?

A. The filter's lifespan
C. The filter's pressure drops
B. The filter's cost
D. The filter's efficiency in capturing particles

684. Companies must ensure availability of ____________ to address qualification of analytical instruments and equipment.

A. Validation protocol
C. Written procedure
B. Master plan
D. GMP guidelines

685. What is the purpose of line clearance validation?

A. To ensure that the correct materials are used in production
B. To ensure that equipment is calibrated correctly
C. To prevent cross-contamination between batches
D. To ensure that finished products meet quality standards

686. The sampling of raw and packaging materials and their retention has to be described in

A. Written procedure
C. Batch document
B. Laboratory logbook
D. Quality assurance manual

687. What is the acceptable endotoxin limit for depyrogenate equipment?

A. 0.1 EU/mL B. 1 EU/mL C. 10 EU/mL D. 100 EU/mL

688. When should an overkill cycle be employed?

A. Only where the items sterilized can withstand extended exposure to the sterilizing process.
B. When the quality and function of the product to be sterilized remains unaffected by the sterilization conditions.
C. Because the load is heat stable, thermal degradation is of no concern and only the minimum F_0 in the coldest load is considered.
D. F_0 that will provide at least a 12-log reduction of microorganisms with a $D_{121°C}$ in one minute to arrive at $F_0 \geq 12$ as a minimum overkill cycle.
E. All are correct

689. What is a HEPA scanning leakage test?

A. A test to measure the efficiency of a HEPA filter
B. A test to detect leaks in a HEPA filter system
C. A test to measure the airflow of a HEPA filter
D. A test to determine the lifespan of a HEPA filter

690. What is the temperature and duration required for depyrogenation using dry heat?

A. 121°C for 15 minutes
C. 160°C for 2 hours
B. 250°C for 30 minutes
D. 350°C for 1 hour

691. None of the analytical instrument could be used without ____________.

A. Qualification
C. Handling manual
B. Validation protocol
D. Standard test methods

692. What is an overkill cycle in sterilization?

A. A cycle that exceeds the minimum requirements for sterilization
B. A cycle that uses a lower temperature than the minimum requirements for sterilization
C. A cycle that uses a shorter duration than the minimum requirements for sterilization
D. A cycle that does not require validation

693. What is the most common method of overkill cycle sterilization?

A. Autoclaving
C. Dry heat sterilization
B. Chemical sterilization
D. Radiation sterilization

694. Pipe ring main slopes should be kept at a level that allows the system water to drain to a low point drain. What is the guidance value to which the pipe line should be installed?

A. The slope-to-pipe length ratio shouldn't be greater than 1:10.
B. The slope-to-pipe length ratio should be greater than 1:10.
C. The slope-to-pipe length ratio shouldn't be less than 1:100.
D. The slope-to-pipe length ratio should be less than 1:100.

695. What type of chemical indicator is typically used for air removal tests?

A. Integrators indicators
C. Specific/Special indicators
B. Emulators indicators
D. Multiple indicators

696. Which change should **NOT** be categorized as one of minor changes in change control

A. Any SOP, or instructions for the purpose of facility cleaning
B. Change in floor-cleaning substance
C. Vendor name change that have product quality impact
D. Secondary packaging without impact on product quality
E. Regular equipment calibration program

697. There must be a system in place, which may prevent the use of the _______ equipment

A. Unclean
B. Old equipment
C. Non-qualified
D. New

698. What factors should be considered when selecting equipment for bracketing?
    A. The type of equipment being cleaned and the cleaning agent used
    B. The size and complexity of the equipment and the nature of the product being manufactured
    C. The frequency of cleaning and the number of operators involved
    D. The availability of cleaning validation equipment and resources
699. How are CIs placed in the sterilization chamber for an air removal test?
    A. They are placed randomly throughout the chamber
    B. They are placed in the center of the chamber
    C. They are placed in the corners of the chamber
    D. They are placed in the areas with the most air pockets
700. For how long shall be Phase II qualification for water system to be carried out?
    A. Minimum of 30 days
    C. Minimum of 2 weeks
    B. Minimum of 1-year
    D. Minimum of 3 months
701. What is the acceptable result for an air removal test using a chemical indicator?
    A. A color change indicating that air has been removed
    B. No color change indicating that air has not been removed
    C. A temperature reading indicating that air has been removed
    D. A pressure reading indicating that air has not been removed
702. What are the potential causes of an out of specification result?
    A. Analytical error
    C. Sample variability
    B. Instrument malfunction
    D. All of the above
703. What is the purpose of worst-case cleaning validation?
    A. To ensure that all equipment is cleaned to a minimum standard
    B. To determine the maximum possible level of contamination on equipment
    C. To validate the cleaning process under the most challenging conditions
    D. To test the effectiveness of different cleaning agents
704. Who typically conducts a quality audit?
    A. Production workers
    C. Management
    B. Regulatory agencies
    D. Customers
705. What method is commonly used for air removal tests?
    A. BIs B. CIs C. Temperature sensors D. Pressure gauges

706. What is the purpose of bracketing in cleaning validation?

A. To reduce the number of samples required for testing

B. To determine the maximum possible level of contamination on equipment

C. To validate the cleaning process under the most challenging conditions

D. To group equipment with similar cleaning requirements for testing

707. What type of pressure differential is typically maintained in an airlock system?

A. Positive pressure inside the airlock
C. Negative pressure inside the airlock
B. Neutral pressure inside the airlock
D. Variable pressure inside the airlock

708. What is the purpose of HEPA filters in an airlock system?

A. To remove dust and dirt particles from the air

B. To remove bacteria and viruses from the air

C. To remove odors from the air

D. To regulate the temperature and humidity of the air

709. The type of sampling method is typically used for bracketing in cleaning validation?

A. Random sampling
C. Swab sampling
B. Rinse sampling
D. Visual inspection

710. What is the acceptable sterility assurance level (SAL) for half overkill cycle?

A. 10^{-6} B. 10^{-4} C. 10^{-2} D. 1

711. What is the temperature and duration required for an overkill cycle using autoclaving?

A. 121°C for 15 minutes
C. 160°C for 2 hours
B. 250°C for 30 minutes
D. 350°C for 1 hour

712. What is the purpose of a HEPA filter?

A. To remove odors from the air

B. To reduce energy consumption

C. To capture small particles and pollutants from the air

D. All of the above

713. What is the purpose of documenting and reporting analytical deviations?

A. To identify trends and patterns in analytical performance

B. To track the effectiveness of corrective actions

C. To comply with regulatory requirements

D. All of the above

714. Which statement is **CORRECT** about change management
    A. It is not usually necessary to prepare and file during emergency change.
    B. It is not implemented in during the execution of basic research operations.
    C. Like for like changes does not requires change control or revalidation.
    D. Emergency changes occur at times when least expected.
    E. None of the above statements are correct
715. Which one is a key aspect of cleanroom qualification?
    A. Contamination control
    B. Quality system
    C. Risk management
    D. All of the above
716. What is the acceptable HEPA filter leakage area that could be fixed with silicon sealant?
    A. < 0.01%
    B. < 0.05%
    C. < 0.1%
    D. < 5%
717. What is the purpose of ICH Q9?
    A. To provide guidelines for quality control in pharmaceutical manufacturing
    B. To provide guidelines for risk management in pharmaceutical manufacturing
    C. To provide guidelines for clinical trial design and conduct
    D. To provide guidelines for post-marketing surveillance of pharmaceutical products
718. An impurity that is individually listed and limited with a specific acceptance criterion in the new drug substance specification.
    A. Specified Impurity
    B. Identified Impurity
    C. Unspecified Impurity
    D. Unidentified Impurity
719. Which one is **NOT** a type of aseptic process simulation?
    A. Media fill
    B. Glove fingertip test
    C. Airflow visualization
    D. Sterility testing
720. Which one is a common threat to data integrity?
    A. Encryption
    B. Malware
    C. Backups
    D. Firewalls
721. The change control system requires that a changed method be _______ prior to implementation of the change and release of product using the method.
    A. Transferred
    B. Executed
    C. Re-validated
    D. Verified
722. What is the acceptable leakage rate for a HEPA filter?
    A. < 0.01%
    B. < 0.05%
    C. < 0.1%
    D. < 0.5%

723. What is the purpose of an airlock system in HVAC?
    - A. To control the temperature and humidity of the air
    - B. To prevent the entry of contaminants into a controlled environment
    - C. To increase the efficiency of the HVAC system
    - D. To reduce energy consumption
724. What is the purpose of risk evaluation in the risk management process?
    - A. To determine the likelihood of a risk occurring
    - B. To determine the severity of the consequences if a risk occurs
    - C. To determine the overall risk level and prioritize risk control measures
    - D. All of the above
725. What is the importance of regular maintenance and testing of an airlock system?
    - A. To ensure that the pressure differential is maintained
    - B. To ensure that the HEPA filters are functioning properly
    - C. To identify and repair any leaks or damage to the airlock system
    - D. All of the above
726. All reagents are ____________ with the date of receipt, the date the bottle is opened and the initials of the person opening.
    - A. Kept B. Labelled C. Purchased D. Registered
727. The difference between a risk control measure and a risk mitigation measure?
    - A. There is no difference, they are interchangeable terms.
    - B. A risk control measure is proactive, while a risk mitigation measure is reactive.
    - C. A risk control measure reduces the likelihood of a risk occurring, while a risk mitigation measure reduces the impact of a risk if it occurs.
    - D. A risk control measure is used for high-risk events, while a risk mitigation measure is used for low-risk events.
728. Which statement is **CORRECT** about major change in change control categories
    - A. It requires regulatory notification and approval prior to implementing the change.
    - B. It should be handled through the documentation review as preventative maintenance programme without the need of official licensing.
    - C. It needs revalidation or requalification as applicable for the changes that have been made
    - D. A and B E. A and C

729. Metadata provides context and meaning to the data. Which of the following is **NOT** metadata for an electronic weighing record?

A. Unit of measurement
B. Sample weight
C. Date & time stamp
D. Weighing balance ID

730. What is the purpose of investigating an out of specification result?

A. To identify and correct potential issues in the analytical process
B. To ensure compliance with regulatory requirements
C. To improve overall analytical performance
D. All of the above

731. How should an out of specification result be handled?

A. Retest the sample
B. Notify management
C. Investigate potential causes
D. All of the above

732. What is the final step in handling an out of specification result?

A. Implementing corrective actions
B. Retesting the sample
C. Documenting and reporting the deviation
D. Reviewing and updating the analytical method

733. Which process is for managing changes to cleanroom environment or processes?

A. Risk management
B. Change control
C. Quality risk management
D. Quality system

734. Which change should **NOT** be categorized as one of the major changes in change control

A. Change in API vendor with different synthesis of a starting material
B. Processes moved to another site during analytical technology transfer
C. Change in product composition as well as change in process parameters.
D. Change in addition of equipment automatic detection system
E. Compendial change from USP to Ph Eur for quality control test

735. In case the batch proves to be compliant as a result of retesting, ____________.

A. Specific directives must be present for disposition of batch
B. Batch must still be rejected
C. Batch should be re-worked
D. Analysts should be re-trained not to report false incidence

736. What is the primary cause of analytical deviations?

A. Human error
C. Equipment malfunction
B. Sample contamination
D. Method variability

737. What is the difference between a single-door and double-door airlock system?

A. A single-door airlock system has one door, while a double-door system has two
B. A single-door airlock system is used for personnel entry, while a double-door system is used for material entry.
C. A single-door airlock system is less effective at preventing contamination than a double-door system.
D. A single-door airlock system is more expensive than a double-door system.

738. What is an analytical deviation?

A. A mistake made during the analysis of a sample
B. A difference between the expected and actual results of an analysis
C. A change in the analytical method used for an analysis
D. A variation in the equipment used for an analysis

739. What is the most common source of sterile non-viable particulate matter in a cleanroom environment?

A. People
B. Equipment
C. Packaging materials
D. All

740. What is the purpose of an air removal test in sterilization?

A. To ensure that all air has been removed from the sterilization chamber
B. To test the effectiveness of the sterilization cycle
C. To determine the temperature and duration required for sterilization
D. To validate the sterilization process

741. Which one is **CORRECT** about purpose of a change control program?

A. To have a written record of any, and all, changes that occur to assure that changes do not impact product quality attributes
B. To determine the need for action to ensure and document that the system is reproducible and maintained in a validated state.
C. To maintain regulatory commitments and comply with cGMP requirements
D. To provide a single, easy to access the source of information regarding changes
E. All

742. What is the microbial challenge in a media fill test?

A. Introduction of microorganisms into the product

B. Introduction of microorganisms into the sterile environment

C. Introduction of microorganisms into the equipment

D. None of the above

743. There should be an established ____________ for environmental para-meters in the sterility test area, with specified alert and action levels.

A. Monitoring program

B. Operating procedure

C. Test method

D. Policies and guidelines

744. What is the acceptable result for bracketing and worst-case cleaning validation?

A. No detectable residue on any swab sample

B. A predetermined limit of residue on each swab sample

C. A reduction in the level of residue compared to previous cleaning validation results

D. A visual inspection indicating that the equipment appears clean

745. Which one is **NOT** a common source of contamination in a cleanroom?

A. Personnel

B. Raw materials

C. Equipment

D. Natural air flow

746. What is the purpose of environmental monitoring during aseptic process simulation?

A. To detect and identify microorganisms in the environment

B. To ensure that the cleanroom meets the required standards

C. To evaluate the effectiveness of cleaning and disinfection procedures

D. All of the above

747. Which one of the following is **INCORRECT** about change control management?

A. It is foundation of quality system based on cross functional input that it is applicable across all other quality systems

B. It is implemented in during the execution of basic research operations.

C. Arrangements should be in place for the prospective evaluation of planned changes and their approval prior to implementation

D. It is utilized as a means of continual improvement in products and processes

E. Changes at contract manufacturers are subject to a change control system and reported to the contract donor for final approval.

748. How can analytical deviations be prevented by?

A. Using more reliable equipment
C. Increasing the number of QC checks
C. Implementing a robust analytical method
D. All of the above

749. What is the purpose of gowning procedures in a cleanroom?

A. To protect the product from contamination
B. To protect the personnel from hazardous materials
C. To ensure proper ventilation in the cleanroom
D. None of the above

750. Which one is **NOT** a factor in determining the cleanliness level of a cleanroom?

A. Airborne particle count
C. Surface particle count
B. Humidity
D. Temperature

751. What is the purpose of air filtration in a cleanroom?

A. To remove particles and microorganisms from the air
B. To maintain positive pressure in the cleanroom
C. To control temperature and humidity levels
D. None of the above

752. Which one is a common type of sterilization used for heat-sensitive materials?

A. Autoclaving
C. Dry heat sterilization
B. Ethylene oxide gas sterilization
D. Radiation sterilization

753. What is the purpose of environmental monitoring in a contamination control strategy?

A. To detect and identify sources of contamination
B. To evaluate the effectiveness of cleaning and disinfection procedures
C. To ensure compliance with regulatory requirements
D. All of the above

754. Which one of the following is **INCORRECT** about change control management?

A. No changes should be made for any validated, approved equipment, systems, tests, and processes without prior formal review and approval
B. Planned change can be temporary or permanent but always Prospective
C. Updating a procedure with grammatical error demands a change control procedure.
D. Temporary change control can be used for limited time in lieu of planned deviation.
E. Re-validation should be considered as part of change control

755. What is the purpose of risk communication in the risk management process?

A. To inform stakeholders about identified risks and risk control measures

B. To obtain feedback from stakeholders on the effectiveness of risk control measures

C. To ensure stakeholders understand their roles and responsibilities in managing risks

D. All of the above

756. The pore size of the ULPA filter is

A. 0.1-micron B. 0.3-micron C. 0.5-micron D. None

757. What is the purpose of validation in sterilization processes?

A. To ensure that the sterilization process is effective and consistent

B. To reduce the cost of sterilization by using lower temperatures and shorter times

C. To increase production speed by reducing the time required for sterilization

D. None of the above

758. What is the first step in the risk management process according to ICH Q9?

A. Risk identification C. Risk evaluation

B. Risk control D. Risk communication

759. According to ICH classification, the climatic Zone II is categorized as

A. Moderate climate

B. Subtropical and Mediterranean climate

C. Hot/dry climate

D. Hot/humid climate

760. BMS or building management system controls

A. Temperature B. Humidity C. Differential pressure D. All

761. One is **NOT** a common method for controlling contamination in a cleanroom?

A. HEPA filtration C. Laminar flow

B. Electrostatic discharge D. Ultraviolet radiation

762. At which distance Return air openings and ducts should be designed form door opening not to induce flow of air through the doors

A. Not within 0.6 m (2 feet) close to the door openings

B. Exactly within 0.6 m (2 feet) close to the door openings

C. Within 0.6 m (2 feet) close to the door openings

D. It depends on building design

763. Which one is **NOT** a step-in sterile gowning?

A. Hand hygiene
C. Donning a surgical mask
B. Donning a sterile gown
D. Donning sterile gloves

764. The need to monitor microbial viable particulate matter in a cleanroom environment?

A. To ensure compliance with regulatory standards
B. To identify potential sources of contamination
C. To evaluate the effectiveness of control measures
D. All of the above.

765. Generally, stability testing is employed for __________.

A. Delivering evidences of the change in quality of the drug product with time.
B. Confirming shelf life for the drug product.
C. Determining container closure system suitability.
D. All of the above

766. What type of data is typically analysed in GMP trend analysis?

A. Manufacturing process details
C. Cost analysis data
B. Quality control test results
D. All of the above

767. What is the purpose of GMP regulations?

A. To ensure the safety and efficacy of pharmaceutical products
B. To increase profits for pharmaceutical companies
C. To reduce manufacturing costs
D. To expedite the approval process for new drugs

768. What is the recommended storage condition for vaccines?

A. Room temperature
C. Refrigerated at 2-8°C
B. Frozen at -20°C
D. Frozen at -80°C

769. The maximum allowable temperature excursion for storage of pharmaceuticals is?

A. 2°C
B. 5°C
C. 10°C
D. 15°C

770. Which one is a key component of successful process validation?

A. Skipping the process design stage to save time
B. Using unqualified personnel to perform the validation
C. Failing to document the validation activities and results
D. Conducting thorough and well-documented validation activities

771. What is the ideal temperature range for storing pharmaceutical products?

A. 0-5°C B. 5-25°C C. 25-30°C D. 30-40°C

772. What is the role of the FDA in enforcing GMP regulations?

A. To inspect manufacturing facilities and ensure compliance with GMP

B. To develop and implement GMP regulations

C. To approve new drugs for market

D. To conduct clinical trials for new drugs

773. Which storage conditions is **NOT** recommended for pharmaceutical products?

A. Direct sunlight

B. Freezing temperatures

C. Humidity above 60%

D. All of the above

774. Which one of the following is/are **INCORRECT** about cleaning validation?

A. Cleaning procedures for products and processes which are very similar do not need to be individually validated.

B. Cleaning during the manufacture of APIs may be directed at processing steps identified as those with the greater risks of cross-contamination or carry-over of impurities into the quality of the finished API.

C. Residues on the surface of equipment for FPP carry over to the next product is imminent same as for API production the carry-over risk.

D. Cleaning validation must be done to confirm the effectiveness of any cleaning procedure in all the equipment that come into contact with the product.

775. Which one is **NOT** a type of process validation?

A. Prospective validation

B. Concurrent validation

C. Retrospective validation

D. Parallel validation

776. Which statement is **CORRECT** about the change control evaluation phase after its implementation?

A. To confirm the quality objectives were achieved and

B. To ensure there was no unintended deleterious impact on product quality.

C. To ensures that the change does not affect existing state negatively and fulfills all the quality principles associated with that specific change.

D. There should be an evaluation of the first batches produced or tested under the change

E. All

777. For Cleaning validation which one is **INCORRECT** acceptance criteria for LOD and LOQ
    - A. MACO should be set less than LOD and LOQ
    - B. Signal-to-noise ratio for LOD should be about 3:1.
    - C. Limits of Detection (LOD): below the residual limits
    - D. Signal-to-noise ratio for LOQ should be about 10:1.
    - E. Limits of Quantification (LOQ) at the maximum or equal to residual limit.
778. Which statement is **INCORRECT** about change management
    - A. It only starts when GMPs begin.
    - B. It should be put into place before the qualification starts.
    - C. It becomes active upon completion of the commissioning and commences at the very first entry into an equipment qualification protocol
    - D. Like for like changes requires change control or revalidation.
    - E. It is cGMP requirement that mandates the formal evaluation of the consequences of change to products, processes or equipment.
779. What is the purpose of change control?
    - A. To ensure that changes are made in a controlled and systematic manner
    - B. To minimize the risk of errors or defects
    - C. To comply with regulatory requirements
    - D. All of the above
780. What is the purpose of a recall plan?
    - A. To prevent recalls from happening
    - B. To reduce the amount of inventory
    - C. To provide instructions for a recall
    - D. To increase profits
781. Which one is **NOT** a component of aseptic process simulation?
    - A. Microbial challenge
    - B. Media fill
    - C. Sterility testing
    - D. Environmental monitoring
782. Which one is a key component of successful validation, regardless of the type?
    - A. Rushing through the validation process to meet production deadlines
    - B. Failing to involve all relevant stakeholders in the validation process
    - C. Conducting thorough and well-documented validation activities
    - D. Ignoring any deviations or non-conformances that arise during the validation process

783. What is the size range of sterile non-viable particulate matter?

A. Less than 1-micron
C. 1-5 microns
B. 5-10 microns
D. Greater than 10 microns

784. What should be done if a sterile gown is contaminated during donning?

A. Continue with the procedure, as long as the contamination is minor
B. Remove the gown and start again with a new one
C. Apply a disinfectant to the contaminated area and continue with the procedure
D. None of the above

785. What is the purpose of wearing sterile gloves?

A. To protect the wearer from contamination
B. To prevent the spread of infectious diseases
C. To provide a sterile barrier between the wearer and the product
D. All of the above

786. What is the maximum particle size allowed in ISO Class 7/ Grade C cleanroom?

A. 0.5µm
B. 1-µm
C. 5 µm
D. 10 µm

787. Which statement is **INCORRECT** about change control categories

A. A minor change can be reported in the annual product report.
B. A major change may not have an impact upon the identity, quality, purity, strength, stability, safety and efficacy or physical characteristic of the product.
C. A minor change may not have an impact upon the identity, quality, purity, strength, stability, safety and efficacy or physical characteristic of the product.
D. A major change requires regulatory notification and approval prior to implementing the change.
E. A minor change should be handled through the documentation system of the preventative maintenance programme.

788. What is the purpose of monitoring sterile non-viable particulate matter in a cleanroom environment?

A. To ensure compliance with regulatory standards
B. To identify potential sources of contamination
C. To evaluate the effectiveness of control measures
D. All of the above

789. What is the purpose of cleaning validation in **non-sterile** manufacturing?
    A. To ensure compliance with regulatory standards
    B. To prevent cross-contamination between products
    C. To evaluate the effectiveness of cleaning procedures
    D. All of the above
790. What is the maximum acceptable alert limit for microbial viable particulate matter in a cleanroom environment according to WHO or EU guidelines of 2022?
    A. 10 CFU/m^3
    C. 100 CFU/m^3
    B. 1,000 CFU/m^3
    D. There is no acceptable limit
791. What is the purpose of environmental monitoring in a cleanroom?
    A. To ensure compliance with regulatory standards
    B. To identify sources of contamination
    C. To evaluate the effectiveness of cleaning procedures
    D. All of the above
792. Dust extraction ducting should be designed with sufficient transfer velocity of
    A. 15–20 m/s.
    B. 10–20 m/s.
    C. 10–25 m/s.
    D. 5–10 m/s.
793. What is the purpose of BIs in sterilization validation?
    A. To confirm that the sterilization process has killed all microorganisms
    B. To measure the temperature and pressure during the sterilization process
    C. To monitor the humidity levels in the sterilization chamber
    D. None of the above
794. Which one is a common method for detecting microbial viable particulate matter in a cleanroom environment?
    A. Air sampling
    C. Both A and B
    B. Surface swabbing
    D. None of the above
795. Which one is **NOT** a method for controlling microbial viable particulate matter in a cleanroom environment?
    A. Use of sterile equipment and materials
    B. Proper gowning and hygiene practices
    C. HEPA filtration
    D. All of the above are methods for controlling microbial viable particulate matter.

796. Low wall air returns can help keep contamination below the height of working surfaces and should preferably located about

A. 30 cm above the floor.
C. 30 cm below the working level
B. 30 cm close to the working area
D. Can't be determined

797. What is the first step in a CAPA process?

A. Identification of the problem
C. Investigation of the problem
B. Implementation of corrective actions
D. Monitoring of its effectiveness

798. What is the first step in investigating an analytical deviation?

A. Retesting the sample
C. Reviewing the analytical method
B. Identifying potential causes
D. Informing management

799. Which materials cannot be sterilized by radiation sterilization?

A. Plastic
B. Glass
C. Metal
D. Rubber

800. Which one is **NOT** a method for controlling microbial contamination in non-sterile manufacturing?

A. Use of preservatives
B. Proper cleaning and sanitation procedures
C. Use of sterile equipment and materials
D. All of the above are methods for controlling microbial contamination.

801. What is the primary purpose of a cleanroom in pharmaceutical manufacturing?

A. To prevent contamination of products
C. To increase production efficiency
B. To reduce manufacturing costs
D. To improve product quality

802. Which one of the following is/are **INCORRECT** about cleaning process validation?

A. Cleaning validation must always aim at the lowest limit of the entire product group.
B. In early production it may be unnecessary to validate equipment cleaning procedures where residues are removed by subsequent purification steps.
C. Residues are not expected to be the same for products cleaned between batches for cleaning process validation, rather expected to be below the predetermined acceptance criteria
D. Cleaning procedures for products and processes which are very similar do not need to be individually validated.
E. None

803. How often should a product quality review be conducted?

A. Quarterly B. Annually C. Every 3 years D. As needed

804. What is linearity in analytical method validation?

A. The ability of the method to produce results that are proportional to the concentration of analyte in the sample.

B. The ability of the method to detect low levels of analyte in the sample.

C. The ability of the method to distinguish between different analytes in the sample.

D. None of the above.

805. The minimum air change rate required for a non-sterile manufacturing facility?

A. 10 air changes per hour C. 20 air changes per hour

B. 30 air changes per hour D. It depends on classroom and activities

806. The most commonly used temperature for Lyophilization _____.

A. -10 to -20°C B. 0 to -10°C C.-30 to -40°C D. None

807. What is the purpose of risk analysis in quality risk assessment?

A. To evaluate the severity of identified risks

B. To identify potential hazards and risks

C. To implement risk control measures

D. To monitor and review the effectiveness of risk control measures

808. What is the minimum air change rate required for a cleanroom?

A. 10 air changes per hour C. 20 air changes per hour

B. 30 air changes per hour D. It depends on cleanroom & activity

809. What is the purpose of process validation in non-sterile manufacturing?

A. To ensure compliance with regulatory standards

B. To identify sources of contamination

C. To evaluate the effectiveness of cleaning procedures

D. To ensure consistency and quality of the manufacturing process

810. What is the purpose of specificity in analytical method validation?

A. To ensure that the method measures only what it is supposed to measure.

B. To ensure that the method is accurate.

C. To ensure that the method is precise.

D. None of the above.

811. Which one is **NOT** a common method for gowning in a cleanroom?

A. Two-piece suit
C. One-piece coverall
B. Sterile gloves
D. Open-toed shoes

812. What is the purpose of a pharmaceutical quality system?

A. To ensure compliance with regulatory requirements
B. To reduce manufacturing costs
C. To increase production efficiency
D. To improve product quality

813. Which one is **INCORRECT** step in the quality risk assessment process?

A. Risk identification
C. Risk analysis
B. Risk evaluation
D. Risk acceptance

814. What is the recommended action for inspection deficiency?

A. Filing a complaint with the regulatory agency
B. Developing a corrective action plan
C. Continuing with current practices
D. Hiring a new quality control manager

815. Which one is **NOT** a common method for non-sterile manufacturing?

A. Tablet compression
C. Liquid filling
B. Aseptic processing
D. Capsule filling

816. If various products are manufactured in the same equipment and cleaned by the same process (SOP), then, a representative of the product can be selected for cleaning validation base on

A. The solubility of the product to be cleaned and difficulty of cleaning
B. The calculation of residue limits based on potency, toxicity and stability
C. Grouping approach products can be selected for cleaning
D. A and B
E. All

817. What is a recommended action for addressing GMP deficiency related to employee training?

A. Firing all non-compliant employees
B. Issuing warnings to non-compliant employees
C. Reducing production output until employees are trained
D. Conducting additional employee training on GMP requirements

818. What is the maximum batch size for terminal dry heat sterilization?

A. 1000 units B. 10,000 units C. 100,000 units D. 1,000,000 units

819. What is **NOT** a recommended action for addressing a GMP deficiency?

A. Implementing new quality control procedures
B. Conducting an internal investigation
C. Ignoring non-compliant practices
D. Developing a corrective action plan

820. Which type of validation is conducted during routine production to ensure that the process remains in a state of control?

A. Prospective validation
C. Retrospective validation
B. Concurrent validation
D. Revalidation

821. What is the main difference between Class I and Class II medical devices?

A. Class II devices require pre-market approval from the FDA
B. Class II devices are non-invasive, while Class I devices may be invasive
C. Class II devices have a higher risk of harm to patients than Class I devices
D. Class II devices are more complex than Class I devices

822. Which type of medical device requires the most rigorous testing and evaluation before being approved for use?

A. Class I B. Class III C. Class II D. Class IV

823. What is the main responsibility of the manufacturer in ensuring compliance for medical devices?

A. Conducting clinical trials to evaluate safety and efficacy
B. Developing and implementing a quality management system
C. Ensuring the product meets all regulatory requirements
D. Marketing the product to healthcare providers and consumers.

824. Which one is **NOT** a component of a pharmaceutical quality system?

A. Quality risk management
C. Change control
B. Employee training
D. Cost reduction strategies

825. What information is typically included in a product quality review?

A. Manufacturing process details
C. Cost analysis data
B. Quality control test results
D. All of the above

826. What is the primary factor that determines the classification of a medical device under GMP regulations?

A. Risk to patient health
B. Availability of materials
C. Cost of production
D. Aesthetics

827. What is the purpose of change control in a pharmaceutical quality system?

A. To ensure that changes are made in a controlled and documented manner
B. To reduce manufacturing costs
C. To increase production efficiency
D. To improve product quality

828. What is the purpose of a product quality review?

A. To identify areas for cost reduction in the manufacturing process
B. To ensure compliance with regulatory requirements
C. To improve the overall quality of the product
D. To increase production efficiency

829. What is the purpose of GMP trend analysis?

A. To identify areas for cost reduction in the manufacturing process
B. To ensure compliance with regulatory requirements
C. To improve the overall quality of the product
D. To monitor and analyse data to identify trends and potential issues of a processes

830. Which one is **NOT** a step in the change control process?

A. Initiating the change
B. Implementing the change without testing
C. Evaluating the change
D. Documenting the change

831. What is the purpose of change control in the pharmaceutical industry?

A. To prevent any changes from being made to a process or product
B. To ensure that all changes are thoroughly tested and validated before implementation
C. To speed up the process of making changes to a process or product
D. To reduce costs associated with making changes to a process or product

832. **NOT** a common method for cleaning in a non-sterile manufacturing facility?

A. Wet cleaning
B. Dry cleaning
C. Steam cleaning
D. Autoclaving

833. What is the level of conductivity in µS/cm for WFI during qualification phase two?

A. 1.3 @ 25^{o}C
B. 2.1 @ 25^{o}C
C. 3.3 @ 25^{o}C
D. 4.7 @ 25^{o}C

834. Which one is **NOT** a benefit of using SIP for sterilization?

A. Reduce risk of contamination
C. Increase efficiency and productivity
B. Decrease regulatory compliance
D. Enhance product quality & consistency

835. When is the right time to test the integrity of the filter before use or before or after or during sterilization?

A. For final filtration, the integrity testing should be done after sterilization as filter properties may have been impacted by sterilization and there may be some flexibility for early-stage sterile filtration
B. For final filtration, the integrity testing should be done before sterilization as filter properties may be impacted by sterilization and there may be some flexibility for later-stage sterile filtration
C. For final filtration, the integrity testing should be done during sterilization as filter properties may impact the sterilization and there may not be flexibility for at any stage sterile filtration
D. A and B
E. B and C

836. Which one is a GMP requirement for personal hygiene?

A. Employees must wear jewellery and accessories while working
B. Employees must wash their hands before and after using the restroom
C. Employees must wear perfume or cologne to mask body odour
D. Employees do not need to cover cuts or wounds on their hands

837. Which type of validation approach involves testing a small sample size to represent the entire process?

A. Risk-based validation
C. Process simulation validation
B. Bracketing validation
D. Matrixing validation

838. If two different products are manufacturing in two modules of one production block, then will you accept the common air handling unit for both pharma area?

A. Unlikely to accept, because of cross-contamination (if re-circulation of return air)
B. Likely to accept, if 100% of fresh air is circulated through the respective area.
C. Contamination control strategy procedure should be taken in account
D. A and B
E. E. All

839. What is the purpose of a gowning and de-gowning procedure?
    A. To provide a comfortable break area for employees
    B. To store raw materials and finished products
    C. To ensure that employees do not bring contaminants into production areas
    D. To conduct quality control testing
840. Who is responsible for conducting a product quality review?
    A. Quality control department
    C. Manufacturing department
    B. Regulatory affairs department
    D. Quality assurance department
841. What does a clean room "ISO class 7" area signify?
    A. 10,000 or less particles of 0.5 µm and larger size exist in a given ft^3 of air.
    B. 10 or less particles of 0.5 µm and larger size exist in a given ft^3 of air.
    C. 100 or less particles of 0.5 µm and larger size exist in a given ft^3 of air
    D. 1,000 or less particles of 0.5 µm and larger size exist in a given ft^3 of air
842. Which one is a critical process parameter?
    A. Temperature during storage
    C. Colour of the product
    B. Size of the packaging
    D. Brand name of the product
843. Which one is a requirement for water systems?
    A. Using untreated water for manufacturing processes
    B. Regular monitoring and testing for microbial contamination
    C. Allowing standing water to accumulate in the system
    D. Using water from an unapproved source
844. What is the first step in a recall process?
    A. Notify regulatory agencies
    C. Notify customers and distributors
    B. Determine the scope of the recall
    D. Investigate the cause of the problem
845. What is the purpose of a change control procedure in GMP utilities?
    A. To provide a comfortable break area for employees
    B. To store raw materials and finished products
    C. To ensure that changes to utilities are properly evaluated and implemented
    D. To conduct quality control testing
846. Which one is **NOT** a stage in GMP cleaning validation?
    A. Pre-cleaning
    B. Cleaning
    C. Post-cleaning
    D. Sterilization

847. Which one is **NOT** a factor considered in determining the level of risk in quality risk assessment?

A. Likelihood of occurrence
C. Severity of consequences
B. Cost of mitigation
D. Detection capability

848. Each document changed bears a revision number and a reason for revision, whereas the final document is reviewed and approved by ____________ unit.

A. QC B. QA C. Validation D. Production

849. What is the purpose of document control?

A. To ensure that all documents are stored in a secure location
B. To ensure that all documents are up-to-date and accurate
C. To reduce the amount of documentation required
D. To increase production efficiency

850. Which one is **NOT** a requirement for document control?

A. All documents must be reviewed and approved by authorized personnel
B. Documents must be stored in a location that is easily accessible to all employees
C. Changes to documents must be documented and approved
D. Documents must be destroyed after 1 year

851. What is the purpose of a document management system?

A. To provide a secure location for storing documents
B. To ensure that all documents are up-to-date and accurate
C. To automate the document control process
D. To reduce the amount of documentation required

852. Which one is a GMP requirement for document control?

A. Using outdated procedures for manufacturing processes
B. Failing to document changes to procedures
C. Allowing unauthorized personnel to approve documents
D. Failing to keep records of document revisions

853. Which stage of process validation involves ongoing monitoring and trending of process data to ensure that the process remains in a state of control?

A. Process design
C. Process qualification
B. Process monitoring
D. Process verification

854. What is the purpose of a document retention policy?
    A. To provide a secure location for storing documents
    B. To ensure that all documents are up-to-date and accurate
    C. To automate the document control process
    D. To ensure that records are retained for a specified period of time
855. Which one is **NOT** a reason for initiating a recall?
    A. A product has been mislabelled
    B. A product has been contaminated with a harmful substance
    C. A product has not been selling well
    D. A product has been manufactured using incorrect ingredients
856. What is the size range of microbial viable particulate matter?
    A. < 0.5 microns B. 0.5-1-micron C. 1-5 microns D. > 5 microns
857. Which one is **INCORRECT** about air containment concept
    A. A clean corridor concept is usually recommended for non-sterile oral solid-dosage form production areas
    B. Air containment pressure differential concept uses a high-pressure differential, low airflow
    C. Sterile products should be manufactured under a pressure cascade regime that is positive relative to atmospheric pressure
    D. Highly potent products should be manufactured under a pressure cascade regime that is negative relative to atmospheric pressure
    E. Air containment displacement concept is used in zones where little or no dust is being generated.
858. Which one is a corrective action that may be taken during a recall?
    A. Continuing to sell the affected product
    B. Issuing a press release stating that the product is safe
    C. Destroying or returning the affected product
    D. Ignoring customer complaints about the affected product
859. Planned changes are intentional and ________ also can be permanent or temporary.
    A. Post approved C. Reviewed
    B. Pre-approved D. Well-thought of

860. Which one is **NOT** a requirement of GMP compliance?

A. Documenting all manufacturing processes

B. Regularly training employees on GMP principles

C. Conducting product testing only after it has been released to the market

D. Maintaining a clean and controlled manufacturing environment

861. Which one is a critical process parameter?

A. Product weight C. Equipment size

B. Temperature D. Operator name

862. What is the purpose of a training program in GMP personnel?

A. To provide a comfortable break area for employees

B. To store raw materials and finished products

C. To ensure that all employees are knowledgeable about GMP requirements and procedures

D. To conduct quality control testing

863. The filter medium used in HEPA filters is made up of……

A. Borosilicate Glass C. Silver Nitrate

B. Pleated fiberglass paper D. Cellulose Acetate

864. A written procedure must address exact number of samples specified for different ______ and batch size, and so on.

A. Batches B. Dosage forms C. Products D. Lot numbers

865. It is good practice to select an action level greater than the alert level, but less than the specification

A. True B. False

866. Cleaning validation is necessarily required for which of non-critical cleaning

A. Cleaning takes place between batches of the same product

B. Cleaning takes place on different lots of the same intermediate in a bulk process

C. Cleaning of floors, walls

D. Cleaning outside of inside a vessel

E. Cleaning following some intermediate steps

867. In cleanroom qualification, what is the term used to describe the process of verifying that the cleanroom meets its intended performance requirements?

A. Validation B. Qualification C. Verification D. Monitoring

868. Who is responsible for ensuring compliance in a manufacturing facility?

A. The CEO of the company
B. All employees in the facility
C. The quality control department
D. The regulatory overseeing the industry

869. What is the drive of GMP compliance?

A. To ensure that products are safe, effective, and of high quality
B. To increase profits for the company
C. To reduce manufacturing costs
D. To speed up the manufacturing process

870. Room containment can normally be achieved by which application

A. The displacement concept low pressure differential, high airflow
B. The pressure differential concept high pressure differential, low airflow,
C. The physical barrier concepts (RABS, Isolators).
D. A and B
E. All

871. How often should a GMP quality manual be reviewed and updated?

A. Once a year
B. Only when there are changes
C. Every five years
D. It does not need to be reviewed

872. What are cGMP requirements for building and facilities?

A. Suitable size, construction and location for quality product manufacturing
B. Facilitate cleaning, maintenance and proper operation for systems and utilities
C. Defined areas of adequate size and space for proper function of the facility
D. Facility Power and water supply in a sequential manner
E. Adequate lighting, ventilations, air filtration, plumbing sewage, toilet facilities

873. Who should be involved in developing a quality policy?

A. The CEO of the company
B. All employees in the facility
C. The quality control department
D. The regulatory agencies

874. What is the purpose of a quality manual?

A. To outline the company's marketing strategy
B. To provide guidance on how to manufacture products
C. To ensure compliance with GMP regulations
D. To set financial targets for the company

875. Who is responsible for maintaining and updating the quality manual?

A. The CEO of the company
C. The quality control department
B. All employees in the facility
D. The regulatory agencies

876. Under which circumstances would personnel be disqualified from entering cleanrooms?

A. A negative trend is found on personnel monitoring.
B. Associate has exceeded the requalification period.
C. After a critical observation and/ or investigation of inappropriate behaviors.
D. An associate has not entered the area for an extended length of time
E. All

877. Which one is **NOT** a method for controlling sterile non-viable particulate matter in a cleanroom environment?

A. HEPA filtration
C. Electrostatic discharge control
B. Proper gowning and hygiene practices
D. Use of non-sterile equipment

878. What is the consequence of **NOT** having a quality manual?

A. The company may face fines or legal action
B. The company may increase profits
C. The company may have more flexibility in manufacturing processes
D. The company may have a better reputation in the industry

879. What is sterile parametric release?

A. A process for releasing sterile products based on predetermined parameters
B. A process for releasing non-sterile products based on predetermined parameters
C. A process for sterilizing products based on predetermined parameters
D. A process for testing the efficacy of sterilization

880. Phase III WFI qualification, what is the USP acceptable level of conductivity at 25°C?

A. 1.3 µS/cm B. 2.1 µS/cm C. 3.3 µS/cm D. 4.7 µS/cm

881. Which order is the **CORRECT** for stages of qualification?

A. URS/DS ---FAT----Commissioning---SAT---DQ---IQ---OQ---PQ
B. URS/DS ---SAT----Commissioning---FAT---DQ---IQ---OQ---PQ
C. URS/DQ ---FAT----SAT----Commissioning---DQ---OQ---IQ---PQ
D. URS/DQ ----Commissioning---FAT----SAT---DS---IQ---PQ---OQ
E. URS/DS ---FAT----SAT----Commissioning---DQ---IQ---OQ---PQ

882. What is the acceptable limit for microbial contamination in non-sterile products?

A. 10 CFU/ gram B. 100 CFU/gram C. 1,000 CFU/gram D. No limit

883. Which of the following option is **NOT** correct regarding QA and QC?

A. The process capabilities should be monitored on intermittent basis
B. The measuring equipment's used must have a calibration certificate
C. In process inspections are done during or at the end of process manufacturing
D. Quality assurance depends on the activities of the entire company

884. Which one is **NOT** the objectives of QC system in a pharmaceutical industry

A. There is a day-to-day control maintained over the quality aspects of drug products.
B. Incoming raw materials, in-process goods and finished products are all tested for noncompliance with predetermined quality specifications.
C. Environmental monitoring is performed to make sure products are manufactured, packed and stored under prescribed conditions.
D. Deviations of any nature are reported, adequately investigated and the results are recorded.
E. Analytical methods are developed and validated to assure they stay capable of providing results that are accurate and predictable

885. Which one is **NOT** a factor that affects cleaning validation?

A. Cleaning agent concentration C. Cleaning agent temperature
B. Equipment design D. Manufacturing location

886. Which one of the following is **TRUE** about reprocessing and rework materials?

A. Regular reprocessing of materials is often an indication of a process running under state of control.
B. Reworking is an unexpected occurrence and is pre-approved as part of the marketing authorization.
C. Reprocessing is not a deviation from an existing described process
D. The expiry or retest date of the blended batch should be based on the date of manufacturing date of the newest input material or batch in the blend
E. Reprocessing of a drug product is atypical and rarely results in improving drug purity.

887. What is the advantage of sterile parametric release?

A. It saves time and money C. It ensures 100% sterilization
B. It eliminates the need for sterility testing D. It increases the shelf life of products

888. The purpose of ICH guideline is/are
    A. Ensuring quality, safety and efficacy of drugs.
    B. Harmonization of drug technical requirements.
    C. Avoid duplication of human clinical trials.
    D. Reduce use of animal testing but without a compromise on evaluating efficacy and
    E. All
889. The internal surface roughness (Ra) required for stainless steel tubing used for product transfer and cleaning utilities for vaccines and sterile products as per WHO, 2012?
    A. Ra is not greater than 0.8 microns
    B. Ra is not greater than 0.6 microns
    C. Ra is not less than 0.8 microns
    D. Ra is not less than 0.6 microns.
890. How often should GMP trend analysis be conducted?
    A. Quarterly B. Annually C. Every 3 years D. As needed
891. All are technical measure approach of prevention contamination in production area. **EXCEPT**
    A. Closed systems for processing and product transfer between equipment
    B. Recording of spills, accidental events or deviations from procedures;
    C. Air-locks and pressure cascade to confine potential airborne contaminant
    D. Controlled removal of dust close to source of the contaminant
    E. General separation of equipment washing, drying and storage areas.
892. What is the role of analytical testing in cleaning limit acceptance criteria?
    A. To ensure that equipment and facilities are free from visible dirt and debris
    B. To establish cleaning procedures
    C. To determine the appropriate cleaning agents to use
    D. To measure residual contaminants on equipment and surfaces
893. What is the consequence of **NOT** meeting cleaning limit acceptance criteria?
    A. Equipment and facilities must be re-cleaned
    B. Products cannot be released for distribution
    C. Regulatory agencies may take enforcement action
    D. All of the above

894. What is the role of visual inspection in cleaning acceptance criteria?
    A. To ensure that equipment and facilities are free from visible dirt and debris
    B. To test the efficacy of cleaning agents
    C. To monitor product quality during manufacturing
    D. To establish cleaning procedures
895. What is the role of process validation in sterile parametric release?
    A. To establish predetermined parameters for release
    B. To test the efficacy of sterilization
    C. To ensure compliance with regulatory standards
    D. To monitor product quality during manufacturing
896. Which one is **NOT** a common source of contamination in non-sterile manufacturing?
    A. Raw materials
    B. Personnel
    C. Equipment
    D. Airborne particles
897. **TRUE** statement about reprocessing
    A. Reprocessing involves subjecting a nonconforming or conforming batch to the same process
    B. Reprocessing is subjecting the batch to one or more steps that are apart from the established manufacturing process.
    C. Reprocessed material must not be supported by process validation and stability,
    D. Reprocessing of a nonconforming may occur with a regulatory filing
    E. A reprocessed batch should be given a new batch number.
898. What is the aim of cleaning limit acceptance criteria?
    A. To establish cleaning procedures
    B. To determine the appropriate cleaning agents to use
    C. To ensure that cleaning is effective and consistent
    D. To set acceptable limits for residual contaminants on equipment and surfaces
899. What is the role of analytical testing in determining residue limits?
    A. To ensure that equipment and facilities are free from visible dirt and debris
    B. To establish cleaning procedures
    C. To determine the appropriate cleaning agents to use
    D. To measure residual contaminants in product

900. What is the intent of setting residue limits in cleaning validation?

A. To establish cleaning procedures

B. To determine the appropriate cleaning agents to use

C. To ensure that residual contaminants in products are within acceptable limits

D. To set acceptable limits for residual contaminants on equipment and surfaces

901. To which type of process validation are reworked batches would be subjected to?

A. Prospective validation
C. Concurrent validation

B. Retrospective validation
D. Revalidation

902. What is the purpose of worst-case scenario testing in cleaning validation?

A. To identify the most difficult to clean areas and equipment

B. To determine the maximum acceptable residue levels

C. To ensure that all cleaning procedures are followed correctly

D. To test the effectiveness of different cleaning agents

903. The primary purpose of quality risk assessment in pharmaceutical manufacturing?

A. To identify potential hazards and risks
C. To reduce manufacturing costs

B. To increase production efficiency
D. To improve product quality

904. What is the objective of MACO?

A. To ensure that manufacturing processes are as efficient as possible

B. To reduce the cost of manufacturing pharmaceuticals

C. To establish safe limits for cross-contamination during manufacturing

D. To promote the use of sustainable materials in manufacturing

905. Which stage of process validation involves demonstrating that the process is capable of consistently producing product that meets predetermined specifications?

A. Process design
C. Process qualification

B. Process monitoring
D. Process verification

906. What is the purpose of an aseptic media fill?

A. To test the sterility of the manufacturing environment

B. To ensure accurate tracking and documentation of materials and products

C. To promote the use of sustainable materials in production

D. To establish safe limits for cross-contamination during production

E. All

907. What are the acceptance criteria for worst case scenario testing in cleaning validation?

A. No detectable residue C. Residue below the acceptable limit
B. Residue within the specified range D. Residue above the acceptable limit

908. Potential sources of cross-contamination in pharmaceutical manufacturing?

A. Equipment used in the manufacturing process
B. Personnel working in the manufacturing area
C. Raw materials used in the manufacturing process
D. All of the above

909. Which one is **NOT** a parameter used in sterile parametric release?

A. Sterilization time B. Temperature C. Pressure D. Product colour

910. **INCORRECT** statements regarding air containment using a displacement concept

A. Air is supplied into the corridor, from where it flows through the doorway and into the room, and gets extracted out from the back of the room.
B. A preferred method of air containment that works with high pressure differential, low airflow,
C. It is often used in areas where dust generation is high.
D. The room door must be kept closed and air entry is through a door grille.
E. The air should move with a velocity that’s high enough to ensure there is no turbulence in the doorway that may cause dust to escape.

911. Which one is a key requirement of production reconciliation?

A. Using outdated software and technology
B. Ignoring discrepancies in inventory records
C. Conducting regular reviews and audits of reconciliation processes
D. Allowing untrained personnel to perform reconciliation tasks

912. Which one is **NOT** a common type of equipment used in non-sterile manufacturing?

A. Tablet press B. Coating machine C. Lyophilizer D. Autoclave

913. How can GMP be implemented effectively in production reconciliation?

A. By establishing clear procedures and protocols
B. By providing training and ongoing education for personnel
C. By conducting regular audits and inspections
D. All of the above

914. What is the acceptable limit for sterile non-viable particulate matter as per FDA

A. 100/m^3 particles
C. 1,000/m^3 particles
B. 10,000/m^3 particles
D. There is no acceptable limit

915. What is the purpose of an aseptic media fill?

A. To ensure that the manufacturing process is sterile and free of contamination
B. To reduce the time required for production reconciliation
C. To promote the use of sustainable materials in production reconciliation
D. To establish safe limits for cross-contamination during production reconciliation

916. Which type of glass container is suitable for storing highly acidic or alkaline?

A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

917. Which one of the following is/are **NOT** part of the batch release procedure?

A. Subsequent re-test results lie within specifications
B. Laboratory error is identified
C. No process aberrations have been revealed by the review
D. Results from the batch's in-process tests, dissolution, content uniformity and other important tests match the passing re-test results
E. The process is found to be robust, and other batches have not been affected

918. What should be included in cleaning validation plan?

A. The cleaning method to be used
C. The frequency of cleaning
B. The acceptance criteria for cleanliness
D. All of the above

919. Which one of the following is/are **TRUE** about cGMP procedure?

A. Any procedures or specifications that are likely to impact the strength, identity, purity and quality of the drug product must be approved by the QA.
B. Only starting materials which have been released by the production department and which are within their retest date should be used
C. Incoming materials should be physically and administratively quarantined immediately after receipt or processing,
D. Intermediate purchased should be handled on receipt as though they were starting materials.
E. Generally, non-critical weighing or measuring of materials require witnessing by supervisors.

920. How can MACO be applied to ensure product quality?

A. By establishing maximum allowable limits for contaminants

B. By monitoring and controlling the manufacturing process

C. By implementing effective cleaning procedures

D. All of the above

921. What is the purpose of production reconciliation?

A. To ensure accurate tracking and documentation of materials and products

B. To reduce the time required for production reconciliation

C. To promote the use of sustainable materials in production reconciliation

D. To establish safe limits for cross-contamination during production reconciliation

922. Which type of validation is conducted when changes are made to the process or equipment that may impact product quality?

A. Prospective validation C. Retrospective validation

B. Concurrent validation D. Revalidation

923. Which type of glass is recommended for packaging of highly sensitive drugs?

A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

924. Which one is **NOT** a recommended practice for preparing for a GMP inspection?

A. Conducting internal audits

B. Ensuring documentation is up-to-date and accurate

C. Hiding non-compliant practices from inspectors

D. Providing employee training on GMP requirements

925. Which type of glass is suitable for packaging of non-parenteral products?

A. Type I glass C. Type III glass C. Type II glass D. Type IV glass

926. Which one is **NOT** a requirement for maintaining GMP compliance?

A. Regular equipment calibration and maintenance

B. Documented personnel training records

C. Consistent adherence to quality control procedures

D. Maximizing profits at all costs

927. What is the first step in addressing inspection deficiency?

A. Denying the deficiency C. Developing a corrective action plan

B. Ignoring the deficiency D. Blaming employees for the deficiency

928. Which one is GMP violation?
    - A. Failing to follow proper cleaning procedures for equipment
    - B. Completing documentation accurately and on time
    - C. Providing employee training on unrelated topics
    - D. Allowing untrained personnel to operate equipment
929. A factor to be considered in selecting worst case scenarios for cleaning validation is?
    - A. Equipment size and complexity
    - B. Cleaning agent compatibility
    - C. Product solubility and potency
    - D. All of the above
930. The purpose of OQ in HVAC is to
    - A. Verify and document that an HVAC system provides acceptable operational control under “at-rest” conditions.
    - B. Verify and document that an HVAC system provides acceptable operational control under “in-operation” conditions.
    - C. Verify and document that an HVAC system provides acceptable operational control under “at-rest” and “in-operation” conditions.
    - D. Verify and document that an HVAC system provides acceptable operational control under “in-built” conditions.
    - E. A and B
931. Which one is a benefit of maintaining to compliance?
    - A. Increased risk of product recalls
    - B. Decreased regulatory oversight
    - C. Improved product quality and safety
    - D. Reduced need for personnel training
932. Which one is **NOT** a practice for responding to inspection findings?
    - A. Denying the existence of non-compliant practices
    - B. Developing a corrective action plan
    - C. Implementing corrective actions in a timely manner
    - D. Communicating with regulatory agency regarding progress
933. Which one is **NOT** a recommended practice for addressing inspection deficiency?
    - A. Conducting an internal investigation
    - B. Identifying the root cause of the deficiency
    - C. Ignoring the deficiency and hoping it goes away
    - D. Implementing corrective actions in a timely manner

934. The potential consequence of failing to address inspection deficiency is?

A. Improved product quality and safety	C. Increased regulatory oversight
B. Reduced need for personnel training	D. Increased market share

935. Which one is a corrective action for inspection deficiency?

A. Ignoring the deficiency and hoping it goes away

B. Blaming employees for the deficiency

C. Implementing new marketing strategies

D. Conducting additional employee training on GMP requirements

936. Which one is **NOT** a factor considered in cleaning acceptance criteria?

A. Type of product being manufactured	C. Type of cleaning agent used
B. Time of day when cleaning is performed	D. Type of equipment being cleaned

937. Which one is **INCORRECT** a practice for preventing future inspection deficiencies?

A. Conducting regular internal audits

B. Ensuring documentation is up-to-date and accurate

C. Ignoring non-compliant practices

D. Providing employee training on GMP requirements

938. **FALSE** about the importance of cleaning validation

A. Fulfill the regulatory requirements and quality is improved

B. High level of assurance to achieve the same level of cleanliness all the time.

C. Ensures there are no chances of cross-contamination.

D. Microbial growth is rendered

E. With proper cleaning, equipment life is augmented & downtimes are reduced.

939. Which type of validation is conducted before production begins and involves testing the process using predetermined criteria?

A. Prospective validation	C. Retrospective validation
B. Concurrent validation	D. Revalidation

940. What is the purpose of a BIs in SIP sterilization?

A. To monitor temperature during the sterilization process

B. To ensure proper steam flow and distribution

C. To confirm the effectiveness of the sterilization process

D. All of the above

941. Which materials are **NOT** compatible with VHP sterilization?

A. Stainless steel B. Glass C. Rubber D. Plastic

942. Which one is **NOT** a consideration when designing a SIP system?

A. Material compatibility with steam and high temperatures
B. Proper sealing and insulation to prevent steam leakage
C. Availability of clean steam for sterilization
D. Use of only single-use components to prevent contamination

943. Which one is **NOT** a factor that impact the effectiveness of steam sterilization?

A. Load size and configuration C. Sterilization time and temperature
B. Steam quality and purity D. RH levels of sterilization chamber

944. What is the purpose of a cleaning validation for SIP?

A. To monitor temperature during the sterilization process
B. To ensure proper steam flow and distribution
C. To confirm the effectiveness of the cleaning process
D. To identify hot and cold spots in the sterilization chamber

945. Multiple and frequent alert level excursions should be treated as an action level excursion and appropriate corrective measures must be taken

A. True B. False

946. How often should a company review and update their CAPA process?

A. Every 5 years C. Every 2 years
B. Annually D. As needed or when changes occur

947. Which one is **NOT** a requirement for GMP in steam sterilization?

A. Regular validation of the sterilization process
B. Proper documentation of sterilization cycles
C. Use of only single-use components
D. Regular maintenance and calibration of equipment

948. The purpose of a temperature mapping for steam sterilization?

A. To monitor temperature during the sterilization process
B. To ensure proper steam flow and distribution
C. To confirm the effectiveness of the sterilization process
D. To identify hot and cold spots in the sterilization chamber

949. What is the minimum exposure time required for VHP sterilization?

A. 15 minutes B. 30 minutes C. 45 minutes D. 60 minutes

950. **FALSE** statement about reworking

A. Rework of a nonconforming requires regulatory filing.
B. Reworking involves subjecting a nonconforming or conforming batch to a different process such as changing from the original process
C. Reworking is subjecting batch to one or more steps that are part of established manufacturing process.
D. A reworked batch should be given a new batch number.
E. Reworking often alters the chemical structure of the material

951. What is the purpose of a BIs for steam sterilization?

A. To monitor temperature during the sterilization process
B. To ensure proper steam flow and distribution
C. To confirm the effectiveness of the sterilization process
D. All of the above

952. Who is typically responsible for leading the CAPA process within a company?

A. Human resources department
B. Sales department
C. Quality assurance department
D. Marketing department

953. How can GMP be implemented effectively in aseptic media fill?

A. By establishing clear procedures and protocols
B. By providing training and ongoing education for personnel
C. By conducting regular audits and inspections
D. All of the above

954. Pilot plant studies are done before taking full scale validation batches in order to

A. To optimize the manufacturing process conditions at plant level
B. To confirm the suitability of equipment's used for manufacturing
C. To confirm the consistency of quality of product manufactured at plant level
D. To optimize the manufacturing process conditions, confirm suitability of equipment's, consistency of quality of products manufactured at plant level

955. WFI contains bacteriostatic agents when in containers of

A. 100 mL of less B. 30 mL of less C. 50 mL of less D. 10 mL of less

956. Grade A aseptic area used for manufacturing of ophthalmic solutions prepared by membrane filtration comprises of:
   A. Not more than 100 particles per cubic meter of size 0.5 microns
   B. Not more than 100 particles per cubic foot of size 0.5 microns
   C. Not more than 1000 particles per cubic foot of size 0.5 microns
   D. Not more than 1000 particles per cubic meter of size 0.5 microns
957. What is the typical temperature range used for SIP sterilization?
   A. 50-100°C B. 100-150°C C. 150-200°C D. 200-250°C
958. Which one is a requirement for sterilization in place?
   A. Regular validation of the sterilization process
   B. Use of only single-use components
   C. Proper documentation of cleaning procedures
   D. None of the above
959. Which department is responsible for implementing CAPA in an organization?
   A. Human Resources department C. Quality assurance department
   B. Sales and Marketing department D. Finance department
960. Which one is a non-conformance that would require a CAPA process?
   A. A minor typo on a company website
   B. A customer complaint about slow shipping times
   C. A product defect that poses a safety risk to consumers
   D. An employee arriving late to work one day
961. A solvent that dissolves a lyophilized powder or dilutes a solution
   A. Diluent B. Solvent C. Additive D. Admixture
962. Which one is a requirement of a pharmaceutical quality system?
   A. Regular product recalls
   B. Implementation of corrective actions only
   C. Continuous improvement of processes
   D. None of the above
963. The purpose of change control process is to ensure the appropriate level of review, impact analysis, and approval __________ making any change in the approved systems.
   A. After B. During C. Before D. Without

964. Which type of glass is preferably recommended for packaging of parenteral products?

A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

965. What is the goal of QRM in pharmaceutical manufacturing?

A. To eliminate all risks associated with manufacturing
B. To identify and evaluate risks and implement measures to reduce or control them
C. To increase profits by cutting corners on quality
D. None of the above

966. Which one is **NOT** a tool used in QRM?

A. Failure mode and effects analysis
B. Failure trend analysis
C. Root cause analysis
D. None of the above

967. Difference between corrective action (CA) and preventive action (PA)

A. CA addresses existing problems, while PA addresses potential problems.
B. CA is reactive, while PA is proactive.
C. CA focuses on immediate solutions, while PA focuses on long-term solutions.
D. All of the above.

968. The minimum temperature and holding time required for terminal dry heat sterilization?

A. 120°C for 15 minutes
B. 120°C for 30 minutes
C. 140°C for 15 minutes
D. 140°C for 30 minutes

969. What are some potential consequences of failing to comply in aseptic media fill?

A. Contaminated products and risk to patient safety
B. Legal action and fines
C. Loss of customer trust and reputation
D. All of the above

970. What is the first step in the QRM process?

A. Risk assessment
B. Risk control
C. Risk communication
D. None of the above

971. Why is reprocessing of materials is conducted primarily

A. To increase batch size or material yields during processing
B. To obtain more pure material than the previously produced
C. To bring important CQA into conformance with established specifications.
D. All

972. Which type of dry heat sterilization is suitable for LVP products?

A. Terminal dry heat sterilization C. Continuous dry heat sterilization

B. Both A and C D. None of the above

973. Which one is **NOT** a step in the CAPA process?

A. Identify the problem C. Develop a plan for corrective action

B. Implement the corrective action plan D. Evaluate customer satisfaction

974. HEPA filters have capacity to retain particles is as small as __________size of particles with efficiency __________

A. 0.03 µm, 99.97% C. 0.03 µm, 99.9%

B. 0.003 µm, 99.97% D. 0.3 µm, 99.99%

975. Which is **NOT** a requirement for the reprocessing of rejected products

A. Only in exceptional situations and after a risk assessment has been carried out

B. In accordance with approved manufacturing instructions by production manager

C. Documentation and compliance with the specifications

D. Implementation of stability studies

E. Report/evaluation in PQR/APR

976. What is the maximum batch size for continuous type dry heat sterilization?

A. 1000 units B. 10,000 units C. 100,000 units D. 1,000,000 units

977. Airflow patterns within cleanrooms and zones should be visualized

A. To make sure that there is no ingress from lower-grade to higher-grade areas

B. To demonstrate that air does not flow/travel from less clean areas such as the floor or equipment, thus transferring contaminants to the higher-grade areas.

C. The airflow direction and its uniformity of velocity conform to the design and performance specifications

D. To determine compliance.

E. All

978. The purpose of a validation protocol is

A. To list the procedure, tests and acceptance criteria.

B. To provide an overview of the whole programme.

C. To record the results of tests carried out during validation.

D. All of the above.

979. Which one is **NOT** possible reasons for rework products could be:
    - A. Ordered quantity exceeds the required quantity
    - B. Remaining shelf life is long for further distribution
    - C. Damage to or changes made to the packaging materials
    - D. Errors made by operators or Mechanical defects in the system during the manufacturing process
    - E. Ambiguity in the documentation or uncertainty about the process quality
980. For preparations intended for parenteral administration USP requires the use of _______ as pharmaceutical aid **EXCEPT.**
    - A. Water for injection C. Sterile water for injection
    - B. Bacteriostatic water for injection D. Purified water
981. What is the purpose of a root cause analysis in the CAPA process?
    - A. To identify the underlying cause of the problem
    - B. To determine who is responsible for the problem
    - C. To develop a plan for corrective action
    - D. To evaluate the effectiveness of the corrective action plan
982. Which type of glass is suitable for storing non-aqueous liquids and dry powders?
    - A. Type I glass B. Type III glass C. Type II glass D. Type IV glass
983. What is the advantage of using VHP sterilization over other methods?
    - A. Effective against spores and viruses C. Faster than EtO
    - B. Cheaper than EtO D. None of the above
984. Put the following CAPA processes in the correct order.
    - I. Evaluation,
    - II. Investigation and Analysis
    - III. Identification
    - IV. Implementation Action Plan and Following Up
    - V. Creating an Action Plan
    - A. III, II, I, V, IV C. II, III, I, V, IV
    - B. III, I, II, V, IV D. V, III, II, I, IV,
985. Which type of glass has the lowest chemical resistance?
    - A. Type I glass B. Type III glass C. Type II glass D. Type IV glass

986. Which of the following is(are) not a way to demonstrate the accuracy of a method?

    I Determine the limit of detection for the method.

    II Analysis of a certified reference material in a matrix similar to the sample.

    III Compare the results between two or more different analytical methods.

    IV Analyze a blank sample with a known amount of analyte in the same matrix as the sample.

    A. Only IV B. II and III C. I and III D. Only I

987. Which one is a process validation protocol?

    A. SOP B. Batch record C. VMP D. Change control

988. What is bioequivalence?

    A. Comparison between 3-year-old drugs to the same new drug.
    B. Comparison between drugs to another drug.
    C. Comparison between a drug's specific characteristics to a defined set of standards.
    D. Comparison between two or 3 characteristics of a drug to the same characteristics of a different drug.
    E. B and C

989. For APIs, retest rather than expiration date terminology is commonly used.

    A. True B. False

990. What are the factors affecting product stability?

    A. The intrinsic stability of the APIs
    B. The unit operations associated with the manufacturing process
    C. Environmental factors (external, internal, and microenvironment)
    D. The materials and functionality associated with any packaging system
    E. Each ingredient can affect the stability of drug substances and dosage forms.
    F. All

991. Which one of the following is **NOT** applicable for bracketing stability design?

    A. If different excipients are used among strengths.
    B. If tested samples are not the extremes.
    C. If different strengths of formulations
    D. If different container size or fill volume with the same container closure system.
    E. A and B

992. Which of the following ICH guidelines addresses the validation of analytical procedure?

A. ICH Q2(R1) B. ICH Q3B C. ICH Q3C D. ICH Q3D

993. Which one is a corrective and preventive action under CAPA?

A. Conducting regular training sessions for employees
B. Implementing a new quality control process
C. Replacing a faulty machine part
D. None of the above

994. Which stage of process validation involves identifying CPPs and acceptable ranges?

A. Process design C. Process qualification
B. Process monitoring D. Process verification

995. **INCORRECT** about ISO 14644-1 sample volume and sampling time per location

A. The volume to be sampled at each location should be at least 2 liters of air, with a minimum sampling time of 1 minute to detect a minimum of 20 particles.
B. The sampling method is only for the purpose of prequalification.
C. If the test failed, the test can only be repeated once with an increased number of sampling points
D. Averaging of sampling points allowed for both at rest and in operation,
E. At least a factor of 10 different from the first particle size if classification is to be extended to a second particle size

996. Commissioning should be performed at the customer's site SAT, after DQ and FAT

A. True B. False

997. **INCORRECT** statement about on-going stability programme is

A. Determine that the product remains, and can be expected to remain, within specifications under the labelled storage conditions.
B. Provides an additional means for detecting "drift" in processes or materials that impact product quality.
C. Conducted after any significant change or deviation to the process or package.
D. Any reworking, reprocessing or recovery operation should also be considered for inclusion on-going stability studies.
E. The first two commercial production batches should be placed to confirm the retest or expiry date of a material.

998. Taking corrective action and implementing it in other systems where problems have not yet occurred, to prevent problems from ever occurring:

A. Corrections B. Corrective C. Preventive D. Remedial

999. Which of the following is **TRUE**?

A. Rabbit pyrogen test is quantitative biologic test

B. Pyrogenic effect is high with IM compared to IV injection

C. Greater danger of pyrogens exists in LVP's than SVP's

D. LAL test is in vivo test

1000. An impurity that theoretically can arise during manufacture or storage. It may or may not actually appear in the new drug substance.

A. Specified Impurity

B. Identified Impurity

C. Unspecified Impurity

D. Potential Impurity

1001. Which one is a corrective action under CAPA?

A. Conducting regular training sessions for employees

B. Implementing a new software system for data management

C. Replacing a faulty machine part

D. All of the above

1002. Which of the analytical method studies below is not required for method validation?

A. Method specificity

B. Calibration

C. Linearity

D. Limit of detection

1003. Testing of residual solvent is to be performed

A. For solvents only for solvents “likely to be present”

B. For solvents used or produced in the final manufacturing step

C. For solvents used or produced in previous manufacturing steps not removed by a validated process

D. For solvents properly declared by a validated supplier

E. All

1004. Change control is an important tool, which controls the change by _____________ ownership of proposed change by qualified representative of appropriate discipline.

A. Giving away

B. Documenting

C. Identifying

D. Approving

1005. The filling of a sterile product under aseptic conditions, or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.

A. True B. False

1006. Which one is a class I recalled product according to FDA recall system?

A. Life-saving medication with labelling mix-up
B. Faulty packaging missing batch number or expiry date
C. Non-life-saving medication with wrong labelling
D. Package labelling not written in English language

1007. Package integrity testing is performed for?

A. Dye leak B. Visual inspection C. Vacuum leak D. All of the above

1008. What is a swab in cleaning validation terms?

A. A cotton swab used to collect samples from equipment and surfaces
B. A type of cleaning agent used to remove residues
C. A type of quality control test used to detect residues
D. A method of documentation required by cleaning validation regulations

1009. Alkali leaching from glass is assessed by

A. Water attack test C. Water vapour permeability
B. Arsenic limit test D. Light transmission test

1010. Which technology transfer phases is/are **NOT** matched correctly according to WHO?

A. Project initiation; Supplier and post marketing commitment
B. Project planning; Team establishment, developing protocol & control strategy
C. Project transfer execution; Production, QC testing, AQbD executions plan based
D. Project review and closeout; SPCs, trend analysis, deviation, change control
E. A and D

1011. In DOP test the scanning is performed at which distance from HEPA filter face

A. 15 mm B. 25 mm C. 20 mm D. 40 mm

1012. Which one is **NOT** a worst-case scenario in cleaning validation?

A. Equipment with complex geometry
B. Equipment used for low-potency products
C. Areas that are difficult to access for cleaning
D. Equipment used for high-potency products

1013. In the event of a positive BI, how many loads should be recalled?

A. Only the affected load
C. All loads containing implants
B. All loads back to the last negative BI
D. None

1014. What is the difference between Type I and Type II DMFs?

A. Type I DMFs contain information about the drug substance, while Type II DMFs contain information about the drug product.
B. Type I DMFs contain information about the drug product, while Type II DMFs contain information about the drug substance.
C. Type I DMFs are submitted by the manufacturer, while Type II DMFs are submitted by the regulatory agency.
D. There is no difference between Type I and Type II DMFs.

1015. The principles of technology transfer according ICH Q10 and WHO applies to

A. Transfer from research and development to production sites, and also between two production sites or laboratories.
B. For newly commercialized products as well as to commercial marketed products and investigational products.
C. The technology of manufacturing processes and analytical procedures relating to APIs, intermediates, bulk drug products and finished pharmaceutical products.
D. All

1016. The time or dose required for 1 log reduction in microbial population is calculated by

A. F_H value
B. Z value
C. F_0 value
D. D value

1017. Which one is **INCORRECT** about the V-model logical sequence of defining the scope, execution and qualification stages.

A. PQ is executed and qualified based on User Requirement Specification
B. OQ is executed and qualified based on Functional specification
C. IQ is executed and qualified based on Design specification
D. IQ is executed and qualified based on Design qualification
E. Commissioning is carried out before qualification and validation.

1018. Spray ball CIP cleaning validation; riboflavin test is acceptable for the spray pattern test to show full surface coverage in equipment OQ.

A. True
B. False

1019. Which one is **NOT** the objective of stress testing
   - A. To identify the likely degradation products, and to completely degrade the API.
   - B. To establish the degradation pathways
   - C. To elucidate the intrinsic stability of the molecule
   - D. To validate the stability-indicating power of the analytical procedures used.

1020. If there is a change in the sampling plan, who must review and authorize change before implementation.

   A. Production B. QA C. In-process D. QC

1021. Periodic management review should consider activities such as
   - A. The quality policy and objectives of the PQS
   - B. The results of audits, analysis of data trending results and other assessments
   - C. Complaints and the status of CAPA to prevent a potential problem or a recurrence
   - D. Any follow-up actions from previous reviews and any changes affecting PQS
   - E. Product characteristics meeting quality safety and efficacy

1022. Accelerated stability testing is done to _____?

   A. Predict shelf life of the formulation C. Predict dissociation constant

   B. Predict diffusion constant D. Determine activation energy

1023. Which one of the following is **INCORRECT** about stability study according to WHO?
   - A. The retest period or shelf life should be derived from stability testing data.
   - B. For stability studies, common practice is to use a retest date, not an expiration date.
   - C. Retest date is assigned to drug substance whereas expiry date is to drug product.
   - D. Intermediate storage condition is recommended for Zones III and IV.
   - E. For a drug product that degrades rapidly, more frequent sampling is necessary.

1024. What type of cleaning is expected to be performed after major preventive maintenance and when area is used after expiration of cleaning validation time of equipment (CHT).

   A. Type A B. Type B C. Type C D. A and C

1025. Level of protection and air cleanliness for different areas should be evaluated based on
   - A. The product being manufactured
   - B. The process of manufacturing
   - C. The product's susceptibility to degradation
   - D. All

1026. Due to the amounts of dust usually generated in a solid dosage facility, most clean area classifications are rated for which occupancy state of cleanroom classification?

A. The "at-rest" condition. C. The "built-in" condition.
B. The "in-operation" condition D. A and B

1027. Which one is class III recalled product according to FDA recall system?

A. Life-saving medication with labelling mix-up
B. A minor container defects or test of a product off
C. Non-life-saving medication with wrong labelling
D. Package labelling not written in English language
E. B and D are the answers

1028. Air change rates are normally determined by which one of the following considerations

A. The supply air's quality and filtration
B. Particulates generated by the manufacturing process and the operators
C. Arrangement of the room and air supply and extract locations
D. Adequate air to achieve containment effect,
E. All

1029. The flow in open channel is laminar if the Reynold's number is

A. < 2000 B. > 4000 C. 2000 to 4000 D. None

1030. Which of the following option is **NOT CORRECT** regarding QA and QC?

A. Process capabilities should be monitored on intermittent basis
B. Measuring equipment's must have a calibration certificate
C. Normally many inspections are done during the process of manufacturing
D. QA depends on the activities of the entire company

1031. Compared to an ISO class 5 area for compounding, how much more particulate matter in room air of particles $\geq 0.5\ \mu m/m^3$ does an ISO class 8 area have?

A. 2x B. 10x C. 100x D. 1000x E. 10,000x

1032. Which one is **NOT** a limitation of gamma irradiation?

A. Thermal degradation of containers
B. Butyl and chlorinated rubber are degraded
C. Hardness and brittleness properties of metals may change
D. Liberation of gases

1033. The efficacy of moist heat sterilization is determined using which spores of organism.

A. Bacillus stearothermophilus C. Clostridium Tetani

B. E. coli D. Clostridium

1034. Which of the following statements is **FALSE**?

A. Bacteria being killed by heat or radiation usually display first-order kinetics.

B. Bacteria being killed by chemicals often fail to display first-order kinetics because their death rate is dependent both on the concentration of the chemical and that of the cellular structure with which it interacts.

C. D values are the most common means of indicating bacterial death rates because they can be used in any situation regardless of the shape of the survivor plot.

D. One of the reasons that steam is a more effective means of killing microorganisms than hot air at the same temperature is that steam possesses latent heat which is released when it condenses.

E. Microbial cells are more susceptible to heat when they are fully hydrated.

1035. According to WHO non-sterile manufacturing, there is no minimum air change rate requirement in regulation for oral solid dosage (OSD) facilities.

A. True B. False

1036. Which of the following statements is **FALSE**?

A. The bacteria which exhibit the most heat-resistant spores are usually thermophiles.

B. Dissolved proteins, e.g. gelatin or serum, are often found to protect bacteria from heat damage.

C. Bacteria normally die more slowly when heated at neutrality rather than at extreme pH.

D. The heat resistance of bacterial spores may be influenced by the chemical composition of the medium in which they were grown.

E. Bacterial spores usually display the greatest heat resistance when tested under conditions of high-water activity.

1037. Which of the following statements about autoclaves is **CORRECT**?

A. They are good at removing pyrogens from glass.

B. They operate below atmospheric pressure.

C. They use saturated steam to kill microorganisms.

D. Gravity displacement systems are suitable for porous loads.

1038. How are samples removed from the dryer without stopping the cycle and breaking the vacuum?

A. Vacuum equilibrator	C. Sample thief
B. Pressure relief valve	D. Thermocouples

1039. Which of the following statements regarding ultraviolet (UV) radiation is **FALSE**?

A. UV radiation is a form of ionizing radiation that causes the electrons of irradiated molecules to become excited.

B. The principal bactericidal effect of UV light is the formation of thymine dimers between adjacent pyrimidine bases on DNA.

C. Photoreactivation of UV damaged cells results in a light-dependent photo reactivating enzyme splitting the thymine dimers into monomers.

D. The wavelength of optimal bactericidal activity for UV light is 265 nm.

E. UV light is used primarily for disinfection of surfaces, air and water.

1040. Which of the following statements regarding antimicrobial gases is **FALSE**?

A. Ethylene oxide forms explosive mixtures with air but this risk can be reduced by mixing with carbon dioxide.

B. Formaldehyde is more bactericidal than ethylene oxide but its penetrating power is not as good, making it a less useful sterilizing agent.

C. Peracetic acid is a gas at room temperature but it is rather unstable and damages certain materials such as metals and rubber.

D. Hydrogen peroxide is a liquid at room temperature and must be heated to generate the gaseous phase. It has the advantage however, of decomposing to just oxygen and water.

E. Methyl bromide is a gas at room temperature and has good penetrating power, but its antimicrobial properties are inferior to ethylene oxide.

1041. Which statements is **CORRECT** for gaseous sterilization?

A. Gaseous sterilization with ethylene oxide requires a desorption period following the sterilization process.

B. Ethylene oxide at a concentration of 800 to 1200 g L^{-1} can be used.

C. Packaging should not be permeable to air.

D. Ethylene oxide is not flammable in air.

E. Gaseous sterilization is used for heat-resistant products.

1042. Which statements is **CORRECT** about sterility assurance level (SAL)?

A. A SAL of 10^{-6} is the probability that not more than 10^{6} viable microorganisms are present in six items of the product.

B. A SAL of 10^{-6} is the probability that not more than one viable microorganism is present in six items of the product.

C. A SAL of 10^{-6} is the probability that not more than one viable microorganism is present in 10^{6} items of the product.

D. A SAL of 10^{-6} is the probability that not more than six viable microorganisms are present in 10^{6} items of the product.

E. A SAL of 10^{-6} is the probability that not more than 10^{6} viable microorganisms are present in any items of the product.

1043. Which of the following statements about biological indicators is/are **CORRECT**?

A. Bacillus subtilis var. niger is used to monitor the process of radiation sterilization.

B. Bacillus atrophaeus is used to monitor the process of dry heat sterilization.

C. Geobacillus stearothermophilus is used to monitor the process of steam sterilization.

D. Bacillus pumilus is used to monitor the process of dry heat sterilization.

E. Geobacillus stearothermophilus is used to monitor the process of radiation sterilization.

1044. Which of the following statements is **CORRECT** about biological indicators?

A. Biological indicators normally contain vegetative bacteria, of concentration not less than 10^{6} CFU mL^{-1}.

B. Biological indicators must be nonpathogenic.

C. Biological indicators are used to ensure that the physical conditions in a sterilizer have been met.

D. Biological indicators are not particularly resistant to a sterilization process.

E. Biological indicators must be used every time a sterilizer is used.

1045. When testing a batch of products for sterility:

A. Only products from the hottest part of the autoclave should be tested

B. A successful test proves that a batch is sterile

C. Neutralization of antimicrobial activity may be required

D. An isolator and/or clean room is not required

E. Controls are not needed as long as the product passes at the first attempt

1046. How does a filter remove unwanted particle from a solution?

A. Sieving B. Entrapment C. Adsorption D. All of the above

1047. Which studies are usually performed during filter validation?

A. Microbial retention C. Extractables/leachables

B. Filter compatibility D. Product integrity testing E. All

1048. Which of the following statements is **CORRECT** about QA?

A. It is the measurement of degree to which a product satisfies the need

B. Any systematic process used to ensure quality in the process

C. Process of identifying defects

D. It is a corrective tool

1049. Arrange the steps of QA in ascending order?

A. Customer needs, material control, design development, process control, marketing

B. Material control, process control, customer need, design development, finished product

C. Customer needs, design development, material control, process control, finished product

D. Material control, servicing, process control, material control, design development

1050. Obsolete labels, labeling, and packaging that include lot or control numbers must be:

A. Kept in a clean, dry, secure room for use with the next batch

B. Destroyed in a controlled, documented manner

C. Attached to the batch record

D. None of the above

1051. Defects are categorized based upon:

A. The number of the same types of defects

B. The likelihood of the defect being found in inspection

C. The potential risk/impact of the defect if it is not discovered during inspection

D. Answers B and C

1052. AQL represents:

A. The maximum number of each level of defect that can be found during QA inspection without impacting overall batch quality

B. American Quality League

C. The number of major and null defects found in a batch

D. The number of critical and secondary defects found in a batch

1053. Why is that the particles of size ≥ 5 μm is no longer included for Grade A at rest and in operation cleanroom classification and for Grade B "at rest".

   A. Sampling and statistical limitations for particles in low concentrations make classification inappropriate.
   B. In order to specify ≥ 5 μm in association with ISO Class 5, the macroparticle descriptor 'M' may be adapted and used in conjunction with at least one other particle size.
   C. Sample collection limitations for ≥ 0.5 μm and ≥ 5 μm particles in low concentrations and sizes > 1 μm make classification at ≥ 5 μm particle size is inappropriate, due to potential particle losses in the sampling system.
   D. A and C
   E. All are correct reasoning

1054. A change has recently been made with the acquisition of a new and larger fermentation tank. What type of inspection would one expect to receive from the Boards of Health?

   A. Concise inspection
   B. Special inspection
   C. Routine inspection
   D. Follow up inspection

1055. When does a data is legible to meet the regulatory expectations of "Data Integrity"?

   A. All data must be traceable to the applicable instrument, gauge, equipment, and person
   B. The data needs to readable, clear and easy to analyze for others
   C. The data must be available to identify the sources or originality
   D. The information must be recorded directly, immediately & in chronological order, both for the first entry and modification

1056. A company receives a customer complaint for a product that was missing 5 tablets in a bottle of 10 tablets. What must the company's reaction be to the complaint?

   A. Investigation
   B. Send a notice to NRA
   C. Recall
   D. No action required

1057. What does contemporaneously recorded mean as per the ALCOA?

   A. The information must be recorded directly, immediately & in chronological order, both for the first entry and modification
   B. The data is verified as correct via repeatable calculation
   C. The data must be available to identify the sources or originality
   D. The data needs to readable, clear and easy to analyze for others

1058. Select the incorrect statement regarding the inactivated type of vaccines:

   A. Prepared by using heat or radiation for the inactivation of toxins of the microbe

   B. Most effective against bacterial pathogens but less on viral pathogens

   C. Poliovirus and Hepatitis A are common inactivated vaccines

   D. Prepared by using heat or radiation for the inactivation of the microbe

1059. Neutral glass is also called as .

   A. Type I glass B. Type II glass C. Type III glass D. NP glass

1060. Arrange the following preparatory steps that must be taken before entering the cleanroom:

   I. Put on non-shedding gown

   II. Apply a waterless alcohol-based surgical hand scrub to bare hands and allow to dry.

   III. Put on dedicated shoes/shoe covers, hair covers, and face masks.

   IV. Put on sterile powder-free gloves.

   V. Apply a waterless alcohol-based surgical hand scrub to the gloves and allow to dry.

   VI. Complete the proper hand hygiene process.

   A. III, VI, I, II, IV, VI C. II, IV, V, I, VI, III

   B. III, I, VI, II, IV, V D. III, VI, II, IV, V, I

1061. State whether the following statement/s about accuracy and precision is/are **TRUE**

   A. Both analytical properties can be ascribed to results

   B. The two are unrelated

   C. Good precision can only be obtained with good accuracy

   D. Good accuracy can only be obtained with good precision

   E. A and D

1062. Which of the following is under the scope of GLP regulations?

   A. Nonclinical PK studies C. Human clinical studies

   B. Nonclinical toxicology studies D. Pharmacology studies for efficacy

1063. Which of the following statement is incorrect about the Live attenuated vaccine?

   A. It is prepared using whole weakened living bacteria or virus

   B. It can generate a long-term immune response with the administration of a single dose

   C. Measles, MMR, and oral polio vaccine are live attenuated vaccines

   D. It is stable at normal room temperature

1064. The airborne particle classification equivalent for Grade C “at rest and in operation” is ISO 7 and ISO 8, respectively.

    A. True B. False

1065. Which one of the analytical figures of merit is **TRUE?**

    A. Precision decreases with increasing standard deviation
    B. Accuracy decreases with decreasing relative error
    C. Sensitivity increases with decreasing limit of detection and quantification
    D. Selectivity increases with increasing interference

1066. Records of a nonclinical study should be retained for _____after termination of the study

    A. One-year B. Two years C. Three years D. Five years

1067. To achieve successful resolution of deviations which considerations are adequate **EXCEPT**:

    A. A one-size investigation doesn’t fit all situations. Simple errors require simple documentation while more serious deviations require broader investigations.
    B. Human error is rarely a sufficient root cause.
    C. Deviations should be void of timelines.
    D. Always verify information and never assume you are correct without proper data to support your instincts

1068. The assessment of aseptic-processing performance is based on the contamination rate of ≤ 0.1% at 95% confidence has generally been considered as indicative of satisfactory performance in the industry.

    A. True B. False

1069. During a review of a proposed change to a packaging line, you discover a potential compatibility issue between a new material and the existing product. The BEST approach is to:

    A. Defer the change until compatibility testing is complete.
    B. Implement the change with a close monitoring plan.
    C. Approve the change based on supplier assurances.
    D. Recommend the change with the compatibility issue documented but not addressed.

1070. Consider a sterilization process in which the achieved SAL value is 1.8×10^{-11}. What was the initial bacterial load before sterilization if the SAL value reached after reduction of 13 log steps?

    A. 18 B. 180 C. 1800 D. 1.8

1071. The intent of the process simulation is to confirm the acceptability of the processing procedures with sterilized equipment, and also to validate the sterilization of the product by the filtration system.

A. True B. False

1072. A manufacturer plans to outsource a critical step in their manufacturing process. When evaluating the change control plan for this outsourcing, the inspector should focus on:

A. Reviewing the qualifications of the new outsourcing facility.
B. Assessing the impact on the overall operational efficiency.
C. Verifying the cost-effectiveness of the outsourcing arrangement.
D. Ensuring the outsourcing contract includes marketing exclusivity.

1073. The PQS investigation and testing procedure for suspected defects are reviewed as which type of GMP inspections?

A. Routine type of GMP inspections C. Follow-up type of GMP inspections
B. Concise type of GMP inspections D. Special type of GMP inspections

1074. During a recall investigation, you trace the potentially defective product to specific customer lots. The **MOST** effective recall strategy would involve:

A. Issuing a press release to warn the general public.
B. Notifying affected customers directly with clear instructions.
C. Recalling all product batches manufactured in the same timeframe.
D. Requesting wholesalers to return any potentially affected stock of any product.

1075. Which information should be included in the deviation management records?

A. Investigation B. Root cause C. Conclusion D. All of the above

1076. During “at rest”, the Grade B cleanroom needs to meet a maximum of 3,520 particles (0.5 µm) per cubic meter. In operation, the number of permitted airborne particles increases to 352,000 (0.5 µm) for each cubic meter of air.

A. True B. False

1077. Batch release for a new sterile product should include review of:

A. Raw material certificates of analysis only.
B. Aseptic processing process data and media fill results.
C. Packaging line performance for the finished product batch only.
D. Marketing materials for the product launch.

1078. A company A gets products manufactured under contract agreement by another company B, the QC unit of company B has the authority to approve or reject those products manufactured, packed, processed or held by company B for company A.

A. True B. False

1079. To ensure ongoing competence of personnel performing aseptic processing, the **MOST** effective training approach would involve:

A. Online modules on aseptic technique.
B. Classroom lectures on GMP regulations.
C. Hands-on training with periodic competency evaluations.
D. Self-directed learning with knowledge checks.

1080. HEPA remove 100% of particles that are ≥0.3 microns and most airborne microorganisms.

A. True B. False

1081. The purpose of an Annual Product Quality Review (APQR) is to:

A. Renew marketing authorization for the product.
B. Evaluate trends in product quality and potential risks.
C. Train production personnel on manufacturing procedures.
D. Review customer satisfaction surveys.

1082. Any water used in general cleaning procedure for noncritical areas is typically sterilized, while in critical operation rooms it is treated

A. True B. False

1083. An OOS result for a sterility test is obtained during batch release. The investigation reveals a potential growth promotion issue in the culture media. The BEST course of action includes:

A. Re-testing the batch with a different media lot.
B. Releasing the batch after re-sterilization.
C. Investigating the root cause of the media issue and retesting with a confirmed sterile media lot.
D. Discarding the batch without further investigation.

1084. The type of documentation that should delineate/describe the procedure to follow and how to use the in-process inspection and test data to control a manufacturing process is

A. Work instruction
B. SOP
C. Record
D. Protocol

1085. During an OOS investigation, a review of analyst training records reveals inadequate knowledge of the specific test method. The MOST appropriate action includes:

A. Retraining the analyst on the test method and re-testing the samples.
B. Assigning the analysis to a different qualified analyst for the test method.
C. Accepting the original result and releasing the batch.
D. Issuing a warning to the analyst's supervisor.

1086. The mount of samples taken must be sufficient for the quantity needed for analysis, retesting in case of OOS and ____________ sample.

A. Retention B. Reserve C. Re-Validation D. Stability

1087. Qualification of a filling line should include verification of its ability to:

A. Operate at the maximum production speed.
B. Accurately dispense the correct dosage form and quantity.
C. Clean and sanitize all components effectively.
D. Minimize downtime for maintenance.

1088. Limit of 0.02 N sulphuric acid for Type III glass in powdered glass test is _.

A. 8 ml B. 1 ml C. 7.5 ml D. 8.5 ml

1089. Qualification of a new water purification system should assess its ability to:

A. Produce sufficient volume of water for production needs.
B. Consistently meet the specified water quality requirements.
C. Operate efficiently with minimal operator intervention.
D. Integrate seamlessly with the existing piping system.

1090. Filters functions by which of the following mechanism(s)

A. Sieving or screening
B. Electrostatic attraction
C. Entrapment or impaction
D. All

1091. Annual systems review for a computerized data acquisition system in a manufacturing process should focus on:

A. Verifying hardware functionality.
B. Evaluating data integrity and security measures.
C. Updating software
D. Assessing the system's user interface for ease of use.
E. All

1092. Freeze drying works on the principle of

A. Evaporation of water
B. Liquefaction of ice to water
C. Sublimation of water
D. Heating at the freezing temperature of water

1093. Antigens are vital components of vaccines, and to enhance immune response and prevent contamination, the least commonly used adjuvant used in vaccine development.

A. Formaldehyde
B. Potassium aluminum sulfate
C. Aluminum sulfate
D. Aluminum hydroxide

1094. Understanding the concept of column selectivity is crucial for optimizing separation in HPLC. Selectivity refers to the ability of the column to distinguish between:

A. The potency and purity of the drug product.
B. Different excipients used in the formulation.
C. Closely related chemical compounds in the sample.
D. The analyst performing the analysis and another analyst.

1095. Physical dimension of equipment and accessories- comes under which qualification?

A. Design qualification (DQ)
B. Operational qualification (OQ)
C. Installation qualification (IQ)
D. Performance qualification (PQ)

1096. What should be periodically assessed for the quality of pure steam used for sterilization?

A. Microbial testing, Non-condensable gases
B. Microbial testing, Dryness value and superheat
C. Microbial testing only
D. Non-condensable gases, dryness value, and superheat

1097. Investigation deviations in the manufacturing process is the responsibility of.

A. Stores
B. QA
C. Production
D. QC

1098. Validation of a new HPLC method for assaying a drug product should demonstrate:

A. Method can be performed quickly.
B. Method is user-friendly for analysts.
C. Method is specific for the target compound.
D. Method is cost-effective to run.

1099. In an analytical validation sense what do precision and accuracy, respectively, really mean?

A. Statistical error, systematic error
B. Bias, statistical error
C. Data trueness, individual measurement data variance
D. Individual measurement data variance, data trueness

1100. The term batch document within a cGMP environment relates to:

A. A document which follows all produced medicine

B. A document which follows QC activities relating to a batch of produced medicine

C. A document which follows a batch of produced medicine

D. A document which scrutinizes a batch of raw material

E. A results sheet relating to the quality of manufactured goods

1101. ______is carried out in connection with the introduction of new drug products.

A. Retrospective validation C. Prospective validation

B. Concurrent validation D. Revalidation

1102. A preventive maintenance program for manufacturing equipment should include:

A. Scheduling repairs only when equipment malfunctions occur.

B. Performing routine inspections and servicing to prevent breakdowns.

C. Repainting the equipment to maintain a professional appearance.

D. Focusing on maintenance tasks that are most cost-effective.

1103. Retrospective validation is performed using data from minimum __ consecutive batches

A. One B. Three C. Five D. Ten

1104. Which statemen holds **TRUE**, if product A is cleaned with 5% of detergent X at 80°C for 60 minutes and another product B is cleaned with 5% of detergent X at 80°C for 30 minutes

A. A products A and B should not be grouped together for cleaning validation purposes.

B. It is very difficult to select the representative product because both products have different cleaning SOP time

C. The processes can be grouped together by changing the cleaning time of the product B, for 60 minutes.

D. All are true

1105. According to ISO 9001 inspection and testing comes under which management responsibility

A. Document control C. Data control

B. Process control D. Maintenance control

1106. A cGMP Grade A environment is equivalent to an ISO 5, for both at rest and in operation. This means that whether employees are working or not, the cleanliness inside the cleanroom must maintain Grade A levels (ISO 5).

A. True B. False

1107. Transfer of an established analytical method from one laboratory to another requires verification of:

A. The qualifications of the analysts in the receiving laboratory.
B. The equivalence of the analytical instruments used in both labs.
C. The availability of the same source of reference materials.
D. The marketing authorization status of the product in both regions.

1108. Water attack test is used to identify the alkalinity in

A. Type-I glass
C. Type-II glass
B. Type-III glass
D. All glass types

1109. The primary purpose of a pharmacopeia, such as USP or Ph. Eur., is to provide:

A. Guidance on marketing and promotion of pharmaceutical products.
B. Scientifically verified standards for drug substances and excipients.
C. Information on the therapeutic uses of different medications.
D. Regulations governing the manufacturing of medical devices.

1110. For which of the following filters does integrity tests are intended:

A. Leaf filters B. Drum filters C. Membrane filters D. Edge filters

1111. When evaluating a vendor for pharmaceutical raw materials, a key factor to consider is:

A. The vendor's proximity to the manufacturing facility.
B. The quality management system and manufacturing process controls of the vendor.
C. The cost-competitiveness of the raw materials offered.
D. The vendor's marketing and sales capabilities.

1112. A common saying in GMP GDocP is: If it is not documented it never

A. Reported
C. Happened
B. Analyzed
D. Taught

1113. Effective supply chain traceability for a finished pharmaceutical product allows for:

A. Streamlining the distribution process for faster delivery.
B. Rapid identification and recall of potentially defective batches.
C. Offering discounts to high-volume customers.
D. Promoting the product to a wider audience.

1114. Recall expectations for drugs apply equally to OTC and prescription drugs.

A. True B. False

1115. What is **NOT** mandatory for steam condensate used for direct sterilization of materials or product-contact surfaces?

A. Microbial testing
C. Chemical analysis
B. Sampling schedule
D. Meeting WFI monograph standards

1116. A manufacturer receives an API with a Certificate of Analysis that shows a slightly out-of-specification impurity level. The BEST course of action is to:

A. Reject the API shipment and request a compliant batch.
B. Accept the API and conduct additional in-house testing.
C. Use the API in production as long as the deviation is minor.
D. Negotiate a price reduction with the supplier.

1117. Which one is the minimum exposure time for wrapped goods in a prevac steam cycle at 134°C.?

A. 4 mins B. 5 min C. 3 mins D.10 mins

1118. Aseptic process simulation conditions

A. Personnel interventions
C. Incubation conditions
B. Selection of growth media
D. Inspection of incubated units

1119. When evaluating the change from one excipient supplier to another, the inspector should focus on:

A. The brand recognition of the new excipient supplier.
B. The bioequivalence impact and data between the original and new excipient formulations.
C. The impact on the product's shelf life with the new excipient.
D. The marketing materials used to promote the product with the new excipient.

1120. What should be considered when installing pipes, ducts, and other utilities in cleanrooms?

A. Creating recesses and unsealed openings
C. Ensuring easy access for cleaning
B. Using bright colors for visibility
D. Installing soundproofing materials

1121. Documents should be retained for at least ___years after the expiry of the product.

A. One B. Three C. Five D. Two

1122. If a previously validated process is being transferred to a third-party contract manufacturer or to another manufacturing site which type of validation can be done

A. Design Qualification
C. Concurrent validation
B. Retrospective Validation
D. Prospective validation

1123. An effective contamination control strategy for a cleanroom environment should include:
   - A. Frequent use of a single strong disinfectant to eliminate all microorganisms.
   - B. Maintaining a controlled temperature and humidity, airflow quality and direction to minimize particulate and microbial growth.
   - C. Installing bright lighting for optimal visibility during operations.
   - D. Offering a wide variety of personal protective equipment (PPE) for personnel

1124. Airborne particle counting is a common method used in cleanrooms to monitor:
   - A. Levels of chemical contaminants in the air.
   - B. The presence of viable (living) microorganisms.
   - C. The concentration of airborne particulate matter.
   - D. The humidity levels within the cleanroom environment

1125. Where should major items of equipment associated with hydraulic, heating, and cooling systems ideally be located?
   - A. Inside the filling room
   - C. Outside the filling room
   - B. Adjacent to the product storage area
   - D. Above the aseptic processing area

1126. An HVAC pressure cascade design is often employed in cleanrooms to:
   - A. Minimize noise levels within the cleanroom.
   - B. Maintain a constant temperature throughout the cleanroom.
   - C. Direct airflow from areas with lower to higher contamination risks.
   - D. Maximize the amount of natural light entering the cleanroom.

1127. The final tier in the quality documentation system is ______.
   - A. Records
   - C. Work instructions
   - B. Quality Procedures
   - D. Quality Policies

1128. During a cleanroom inspection, the inspector observes a biohazard sign posted near a specific area. The **MOST** appropriate action includes:
   - A. Ignoring the sign and continuing with the inspection.
   - B. Inquiring about the nature of the biohazard and appropriate precautions.
   - C. Recommending the removal of the biohazard sign as it may be alarming.
   - D. Requesting a detailed risk assessment for the biohazard without further investigation.

1129. The SOP's are reviewed after ______ years
   - A. One
   - B. Three
   - C. Five
   - D. Two

1130. ______is at the apex of Quality Management System.

A. Quality Records
C. Quality Manual
B. Working instructions
D. Quality procedures

1131. What should be in place to prevent hydrophobic bacteria retentive vent filters from being a source of contamination?

A. Regular replacement of the vent filter
B. Heating to prevent condensation on pipeline
C. Chemical disinfection and sanitization
D. Increased flow rate of the water system

1132. Which is the second step in Handling of complaints?

A. Monthly trend analysis
C. Corrective action
B. Technical investigation
D. Receiving of complaints

1133. Electronic records used in GMP compliance should be:

A. Easily editable to reflect changes in procedures.
B. Protected against unauthorized modification or deletion.
C. Printed regularly for archiving purposes.
D. Accessible to all personnel regardless of their role.

1134. Microbial contamination of non-injectable product results in _____.

A. Class I recall
C. Class II recall
B. Class III recall
D. No recall

1135. During a data integrity review, the inspector identifies inconsistencies between raw data and the final reported results. The **MOST** concerning implication is:

A. The data may not accurately reflect the actual observations.
B. The reported results might be slightly higher than the true values.
C. The data may be difficult to locate for future reference.
D. The appearance of the data may not be visually appealing.

1136. Testing of raw materials and finished products is the responsibility of .

A. Stores
B. QA
C. Production
D. QC

1137. Complaint investigation is the responsibility of ____.

A. Marketing department
C. Quality Assurance department
B. Production department
D. Quality Control department

1138. Regular calibration of laboratory instruments is essential to ensure:

A. Efficient operation of the instruments.
B. Accurate and reliable measurement results.
C. Consistency with competitor's equipment performance.
D. User-friendliness for analysts with limited experience.

1139. The documents should be retained for …… months after the expiry date of the product

A. At least 12 months
B. 5 months
C. 6 months
D. 3 months

1140. An effective corrective action plan for a non-conformance should include:

A. A clear description of the problem but no proposed solutions.
B. Specific actions to be taken, timelines, and assigned responsibilities.
C. A lengthy explanation justifying the non-conformance.
D. Punitive measures for personnel who caused the non-conformance.

1141. A purchaser has specified 316 SS as the requirement material to the equipment manufacturer, which qualification will help them to verify the material.

A. Design Qualification
B. Installation qualification
C. Performance qualification
D. Operational qualification

1142. The effectiveness of a self-inspection program relies on:

A. Following a checklist of pre-defined questions without critical evaluation.
B. Including personnel from various departments with expertise in their areas.
C. Focusing solely on identifying major deviations.
D. Assigning blame to individuals who caused any non-conformances identified.

1143. What are the three most important considerations of a validated analytical method?

A. Precision, accuracy, specificity
B. Linearity, LOD, robustness
C. Precision, specificity, linearity
D. Specificity, ruggedness, robustness

1144. If a purchaser has specified that the equipment is going to run in range of 50-150 rpm & will draw a specific amount of power, how will he verify that the equipment is achieving the operational requirements?

A. Design Qualification
B. Installation qualification
C. Performance qualification
D. Operational qualification

1145. Suppose in a manufacturing campaign for product X, there are 3 batches to be manufactured, batch A, batch B, batch C for a given equipment and/or equipment train, if batch A in the campaign is to be followed by batch B in the campaign, which level of cleaning is required

A. Level I B. Level II C. Level III D. Level IV

1146. Which of the following statements are **CORRECT**?

A. ISO QMS is a voluntary system; it is general and is not demanded by the authorities
B. GMP system is general and is not controlled by the regulatory agencies
C. GMP system is professional; it is controlled legally and concerns pharmaceuticals
D. Absolute quality policy system is a part of GMP.
E. A and B F. C and D

1147. The good material management system ensures the following **EXCEPT**

A. Right quality of the product. C. Stocking large amounts of materials
B. Minimize inventory costs D. Right delivery time

1148. Which of the following statements relating to pharmaceutical production are **CORRECT**?

A. Intermittent operations are preferred in pharmaceutical production
B. In pharmaceutical production, the quantity of raw materials is always equal to the quantity of products
C. In continuous manufacturing operations, the state functions remain constant
D. Production procedures can be intermittent, continuous or both

1149. The recommended size of area to be swabbed for environmental monitoring of equipment and apparatus is _.

A. 10 – 15 cm^2 C. 100 – 200 cm^2
B. 24 – 30 cm^2 D. 2 – 3 cm^2

1150. Which of the following can be uses of HEPA filters?

A. The elimination of filaments from large volumes of parenteral solutions
B. The elimination of pyrogens
C. The filtration of solutions of products which cannot be sterilized by heat
D. Purification of the air of aseptic workplaces

1151. The highest air pressure is maintained in ___.

A. Clean Room C. Gowning room
B. Factory Hallway D. Store room

1152. Which of the following statements relating to lyophilization are **CORRECT**?
    - A. Lyophilization is solvent elimination with sublimation
    - B. Dissolution of lyophilized products is quick
    - C. Appropriate vacuum in the work area and appropriate temperature of the products must be ensured during the process
    - D. The actual moisture content of the product must be monitored several times during lyophilization
1153. Which guideline is represented by ICH Q7?
    - A. Quality Risk Management
    - B. Lifecycle management
    - C. Good Manufacturing Practices
    - D. Pharmaceutical Development
1154. Which of the following statements relating to pharmaceutical glass containers are correct?
    - A. Containers made from neutral glass are categorized into hydrolytic class type 2
    - B. Containers made from soda lime-glass are categorized into hydrolytic class type 1
    - C. Containers made from soda lime-glass the surface of which is modified are categorized into hydrolytic class type 3
    - D. Hydrolytic resistance is the resistance of the glass to chemical modifications due to the effects of water
1155. Which of the following are tools of Quality by design **EXCEPT**?
    - A. Critical Quality Attributes
    - B. Risk assessment
    - C. Process Analytical Technology
    - D. Design of Experiments
1156. Bracketing design for stability testing includes .
    - A. Testing samples of all design factors at all time points
    - B. Testing samples of extreme design factors at all time points
    - C. Testing samples of all design factors at half time points
    - D. Testing samples of extreme design factors at half time points
1157. Regulatory audit is also known as .
    - A. First party audit
    - B. Third party audit
    - C. Second party audit
    - D. Fourth party audit
1158. Key positions in a pharmaceutical company should be occupied by .
    - A. Consultants
    - B. Part time personnel
    - C. Full time personnel
    - D. External auditors

1159. Approval of release of finished product is the responsibility of ____.
   - A. Head of Stores
   - B. Head of Quality Assurance
   - C. Head of Quality Control
   - D. Head of Production

1160. Room classification tests in the “at-rest” condition should be carried out .
   - A. With the equipment installed, HVAC operational, but without any operators.
   - B. In the empty room, in the absence of any equipment or personnel.
   - C. During the normal production process with equipment operating under normal conditions.
   - D. With the normal number of personnel present in the room.

1161. Air pressure differentials in a clean room should be checked ______.
   - A. Daily
   - B. Yearly
   - C. Biannually
   - D. Weekly

1162. Installation qualification of an equipment verifies that _____.
   - A. Equipment is operating consistently
   - B. User requirements are incorporated into equipment design
   - C. Equipment is installed and calibrated
   - D. Installed equipment gives quality product consistently for long period

1163. The dispensing of raw materials from Stores must follow the principle of _.
   - A. First Out Then In
   - B. Fast In Fast Out
   - C. Fast Out Fast In
   - D. First In First Out

1164. Following products cannot be manufactured in the same manufacturing facility
   - A. Penicillin products & Antidiabetic products
   - B. Antiviral product & Anti-inflammatory product
   - C. Antiviral product & Antihypertensive product
   - D. Antimalarial product & Anti-inflammatory product

1165. Type III glass is also known as _____.
   - A. Soda lime glass
   - B. Treated Soda lime glass
   - C. Borosilicate glass
   - D. Treated borosilicate glass

1166. The following is verified during operational qualification of an equipment.
   - A. Equipment is installed and calibrated
   - B. Equipment operates consistently within operational limit
   - C. Equipment shows satisfactory performance over long period.
   - D. Equipment is installed and connected to utilities

1167. Maintaining reference standard and retained samples is the responsibility of.

A. Stores B. QA C. Production D. QC

1168. Airlock doors should be equipped with systems that_.

A. Prevent simultaneous opening of both the doors

B. Allow simultaneous opening of both the doors

C. Prevent simultaneous opening of doors by unauthorized persons

D. Allow simultaneous opening of both the doors by authorized persons

1169. Cleaning of the equipment is a part of ______.

A. Periodic maintenance C. Predictive maintenance

B. Corrective maintenance D. Risk based maintenance

1170. The primary documentation to be reviewed during technical investigation of complaints is

A. Name, address, phone number and email of a customer.

B. Distribution records

C. Deviation records

D. Complaint files and batch records

1171. ______is a process that demonstrates a particular instrument produces results within specified limits, as compared to those produced by a traceable standard.

A. Validation C. Qualification

B. Calibration D. Verification

1172. The recommended limits for number of subvisible particles in ophthalmic solutions by light obscuration test as per USP are:

A. Particles of size ≥ 10 microns: 50 per ml and ≥ 25 microns: 5 per mL

B. Particles of size ≥ 20 microns: 50 per ml and ≥ 50 microns: 5 per mL

C. Particles of size ≥ 50 microns: 50 per ml and ≥ 100 microns: 5 per mL

D. Particles of size ≥ 20 microns: 50 per ml and ≥ 100 microns: 5 per mL

1173. ICH Q10 integrates elements of _____ and continual improvement into the quality management system.

A. Profit maximization C. Product lifecycle

B. Competitive analysis D. Investor relations

1174. Which department holds responsibility of quality audits?

A. Inspection B. QA C. Production D. QC

1175. Environmental conditions such as temperature and humidity are controlled during the storage of materials to:
   A. Make the materials easier to transport
   B. Prevent unauthorized access to the materials
   C. Maintain the materials' characteristics and ensure accurate testing results
   D. Reduce the volume of materials stored

1176. As per USP, the limit of fragments visible to the naked eye in fragmentation test for rubber closures is
   A. Not more than 500
   C. Not more than 100
   B. Not more than 50
   D. Not more than 5

1177. Before a piece of equipment is used in production, which types of acceptance testing are typically conducted?
   A. Factory Acceptance Testing (FAT)
   B. Site Acceptance Testing (SAT)
   C. Personal Acceptance Testing (PAT)
   D. Online Acceptance Testing (OAT)
   E. A and B

1178. Hot air oven method of sterilization is used for
   A. Syringes, B. Gloves, C. Fats & Oils D. Catheters

1179. A comprehensive supplier evaluation process should include which of the following methodologies?
   A. Pricing comparisons only
   B. Supplied product or service performance trending
   C. Supplier certification
   D. Personal relationships with vendors
   E. B and C

1180. ______test is specifically used for testing glass containers used for aqueous parenteral.
   A. Light transmission test
   C. Arsenic test
   B. Thermal Shock test
   D. Internal bursting pressure test

Reference

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